

SMALL BUSINESS REGULATORY REVIEW BOARD

Department of Business, Economic Development & Tourism (DBEDT) No. 1 Capitol District Bldg., 250 South Hotel St. 5th Fl., Honolulu, Hawaii 96813 Mailing Address: P.O. Box 2359, Honolulu, Hawaii 96804 Tel 808 586-2594

David Y. Ige Governor

Wednesday, May 20, 2015 ★ 9:30 a.m. No. 1 Capitol District Building 250 South Hotel Street - Conference Room 436

AGENDA

Luis P. Salaveria DBEDT Director

Members

Anthony Borge Chairperson Oahu

Barbara Bennett 2nd Chairperson Kauai

Kyoko Y. Kimura Maui

Harris Nakamoto Oahu

Director, DBEDT Voting Ex Officio

- I. Call to Order
- II. Approval of April 15, 2015 Meeting Minutes
- III. Old Business
 - A. Discussion and Action on Proposed Amendments to Hawaii Administrative Rules (HAR) Title 16 Chapter 95, Pharmacists and Pharmacies, and the Small Business Statement After Public Hearing promulgated by Department of Commerce and Consumer Affairs attached and incorporated as Exhibit 1

IV. New Business

- A. Discussion and Action on Proposed Amendments to HAR Title 13 Chapter 146, **Hawaii State Park System**, Section 6, **Fees**, promulgated by Department of Land and Natural Resources – attached and incorporated as Exhibit 2
- B. Discussion and Action on Proposed New Rules, Real Property Tax Classification Rules, 12, under Section 5A-6.4 of the Kauai County Code 1987, as amended, promulgated by Department of Finance, County of Kauai attached and incorporated as Exhibit 3
- C. Discussion of Proposed Increase in Commercial Ocean Recreation Activities (CORA) Permit Fees by the County of Maui Budget & Finance Department

V. Legislative Matters

A. Status on House Bill 774, HD1 SD1, "Relating to Small Business" – Makes an appropriation to the department of business, economic development, and tourism for the small business regulatory review board to acquire additional staff

VI. Administrative Matter

A. Board's attorney to advise Board members of its powers and duties regarding reviewing administrative rules pursuant to Chapter 201M, Hawaii Revised Statutes (HRS). Also, Board's attorney will advise board members of Public Agency and Meetings Records (Sunshine Law), Chapter 92, HRS, and Code of Ethics, Chapter 84, HRS Small Business Regulatory Review Board May 20, 2015 Page 2

- B. Action and Voting of Board Chair, pursuant to Section 201M-5(c), HRS, and Election of Vice Chair and Second Vice Chair
- VII. Next Meeting: Scheduled for Wednesday, June 24, 2015, at 9:30 a.m., Conference Room 436, Capitol District Building, Honolulu, Hawaii

VIII. Adjournment

If you require special assistance or auxiliary aid and/or services to participate in the public hearing process (i.e., sign language, interpreter, wheelchair accessibility, or parking designated for the disabled), please call (808) 586-2594 at least three (3) business days prior to the meeting so arrangements can be made.

May 20, 2015 ~ SBRRB Meeting Checklist

Member Attendance		Pre Meeting Checklist				
	Airline Preference	From	Details	Attend	Conference Room #436 (Confirm each month)	X
Anthony Borge, Chair 198266	(E) NA	Oahu	Parking Pass	X	Make 12 - 15 copies of rule packages for board packets	×
Barbara Bennett, 2nd Vice Chail		Kawai	Parking Pass	100/	Poll board attendance	Х
utached Kyoko Kimura 198262	(F)	Maui	Parking Pass	X	Prepare TAF's for Director's approval - ASAP (Linda)	×
Harris Nakamoto	NA NA	Oahu	NA	X	Airline booking ASAP - Linda Quilm, Phi	V./
Director's ex officio - Mark Richey	NA E) Oahu	NA	X	Draft Agenda to Chair	×
Robert Cundiff	NA (Oahu	Parky	X	Post approved agenda on 1) SBRRB website, 2) State Calendar, 3) Lte. Governor's Office	
Nancy Atmospera- Walch	W) NA	Oahu	24	X	Send Agendas to those people who requested it -	
Phillip Kasper (Mani)	18263 E	Maui	Care Care Cor Dot	X	Mail approved agenda to Board members, Deputy AG	
Garth Yamanaka	HA	В.І.	Pung	Х	Mail board packets May Will, 13th, 14th	V
					Photographer - Contact David H. Bachara net	No
					Include parking permits in Board members' agenda packets.	X
	STAFF Post Meeting Checklis		Post Meeting Checklist			
Margaret Ahn	/			Yes		
Dori Palcovich				Yes		

Visitors Sign-in-Sheet - Small Business Regulatory Review Board - May 20, 2015

	Name	Title	Organization	Email	Phone
Н	STEVEN HUNT	TAX MANAGAR	n County of Kornaz	shunt@Kanai, 201	(878)241 4225
2	Curt Cotteell	Asut Admin	DLNR STATE PONKS	ASUF Admin DUNK State Portes court, A. Cothella gos, 587-0289	587.0289
3	Here Spater	Pop mar.	DLNR/State Faule	Stopen, O. Sourse &	JE SOCT ?
4	Dan Quinn	Administrator		Dan. Quinn & hawaii, god 5 870290	5.670230
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Maui CORA permit fee six-fold rate hike passed Budget committee

Patricia Cadiz to: Dori Palcovich

05/10/2015 10:30 PM

History:

This message has been replied to and forwarded.

1 attachment



150515.pdf

Aloha Dori,

The May 15 agenda is attached below. I surely don't see where CORA is included on this agenda, however, we have been advised by legal staff that the topics listed are general enough that we should bring our concerns about CORA fees and present our case at the May 15 meeting anyway. So, we are preparing toward that goal. Worse case scenario is that we prepare for the 15th and if we are denied, we will be that much more prepared for May 26, when the Council has the first reading of the budget. Final reading is June 5, so we are really under pressure here.

Problem:

On the final week of budget deliberations, with no notification to permit holders, Maui Budget & Finance Committee has proposed and approved a six fold increase in CORA permit fees.

Background:

CORA (Commercial Ocean Recreation Activities) are required by County ordinance to hold *a* permit. But many businesses saw multiplicative fee increases when policy changed such that each business would pay per activity *and* per park. In our case, our *one* permit morphed into *nine* permits not because we expanded operations, but simply by actions of government. In 2005, my fee tripled from \$500 (one permit), to \$1500 (because three activities). In 2008, it tripled again to \$4500 (one primary location and 3 backup locations).

With the increase in permit fee from \$500 to \$3,000 per permit, now my fee will be \$27,000. Not only is this unaffordable, but CORA operators were not even notified about the discussion until it was passed and done. It was all proposed and passed in the final week of budget discussions unbeknownst to any of the small business owners.

CORA permit holders are all small family owned businesses.

Fees like this are out of reach for small businesses. We have a staff of about a dozen part time employees. My small school is adaptable to changing weather, and offers three sports; Windsurfing, Kitesurfing and Surfing. We will use several locations to accommodate changing weather. We are wind and weather dependent. So when it is windy we do a wind sport, when there is no wind we offer surfing. It is usually one or the other, seldom both. Wind sports and surf sports are usually mutually exclusive. And we only choose and use the best location for the day's conditions. This is for safety that we have alternate access sites. 90% of our business is in one location with two activities, but the ability to offer surfing at my alternate locations during the windless months of winter is vital to our ability to provide year-round employment.

Tax, Rent, and Wages:

Running a legitimate CORA business is expensive. We pay all our state and federal taxes, high insurance, and many other expenses paid into the local economy. We also have employees. We pay their wages, Federal taxes, Hawaii taxes, Social security, Medicare, Disability insurance as well as Federal and State Unemployment Insurances. Our CORA permits require State and Federal Tax clearance certificates each year and a Dept of Labor Letter of Good Standing.

Illegal operators operating in County parks:

Each year more unpermitted operators do business in our county parks and on state lands. These renegades compete directly with the legitimate CORA schools with impunity. They operate openly and illegally yet the County has not been able (or willing?) to prosecute them or bring them into compliance. We lose good staff to the lure of getting paid "cash under the table". These illegal schools can undercut our prices as they have none of the expenses or restrictions of running a legitimate compliant CORA School. We can't afford to absorb the higher permit fee, nor can we raise are prices because of the renegades.

CORA Operators have build their lives around these activities:

Ocean sports instructors like me accumulate lifetimes of knowledge which they share with students. Our instructors follow their passions and teach what they love. This allows them to have a career doing what they love and doing what they are best at. This knowledge, love and respect for the ocean, and their chosen sport are passed along and shared with the community. CORA represents many operators and instructors that have dedicated their lifetimes to teaching these disciplines with love and aloha.

Maui is known to have the best water sports community:

Maui produces some of the world's best athletes and professional ocean sportsmen and women. Maui's unique environment and a vibrant sports community form the catalyst and breeding ground for an internationally recognized watersports community. This community also supports the world's best known professional watersports industry.

Many pro athletes got their start as keiki in our lesson programs. Many of the world's best known ocean athletes put their children into our kids camps and education programs, to prepare them for future careers as pro-athletes or just to be safe ocean lovers. Our ocean sports programs are vital to the community and have many benefits that support a much wider local industry.

CORA impact on wider business community:

Maui's watersports industry has a stake in Maui's CORA community. The watersports industry on Maui includes many of the world's best known manufacturers and brands of watersports equipment in the fields of surfing, windsurfing and kiteboarding. Internationally recognized brands like; Naish®, Cabrinha®, Airush®, Wainman®, Maui Sails®, Ezzy®, Goya®, DaKine®, (and dozens more), are all local community members rooted in the local scene, that have an immense international standing. The majority of these directly and indirectly engage, support or participate with the CORA community, and form part of the deeply embedded community.

The right to access the ocean:

High fees are charged even though no business is transacted in the parks (or beaches) just instruction. Harsh requirements and expensive fees are charged to CORA operators simply for their right to access the ocean. We are strictly controlled - in fact there are 42 pages of Administrative Rules just governing CORA.

Water Safety Instruction:

All CORA instructors are required to be CPR and First Aid certified and are highly skilled and experienced watermen and women. The majority of CORA operators provide water safety instruction. This type of service is a benefit to the community as it reduces accidents and saves lives. Locals and visitors wishing to enter the ocean can do so under the supervision of an experienced and qualified instructor.

Price Hikes will force overcrowding:

Such a proposed fee hike will force CORA schools to abandon permits for alternate locations and keep only the permits for the most popular sites. Currently CORA schools try to have several optional sites on their permits to give them alternate access for changing conditions. Alternate sites are often vital for safety and/or for avoiding overcrowding of prime locations and thereby minimizing user conflicts.

CORA provide Ocean safety where lifeguards are not present.

Too many preventable Deaths and accidents happen on Maui's unguarded beaches. CORA

operators provide safety and supervise their patrons to prevent accidents. CORA instructors also provide a watchful eye on the public, prevent accidents and perform many rescues to the public. CORA instructors are the defacto lifeguards on many unguarded County beaches and also are present outside lifeguard hours on some guarded beaches. Curtailing CORA activity by raising fees, will drive some operators out of business, or discourage others from having permits for alternate sites, and this will have negative effect on general beach user safety.

Public risk, will increase county Liability:

Without CORA operators and easy access to safety education the level of public risk increases in our oceans and on our beaches. COSTCO, Kmart, Walmart, Target, and a plethora of local shops produce and sell all manner of equipment including; surf craft, kayaks, snorkel, and dive gear to the public and visiting tourists.

Public access to ocean safety education:

Does the County really want to reduce or eliminate the amount of Ocean Safety education available to the public? Not only are untrained participants at risk, but they also pose a risk to others and will overburden our limited emergency services.

Millions of tourists will enter the ocean this year with or without CORA supervision. That is because they are sold on the ocean lifestyle dream in images that the tourism industry constantly presents to them. The Maui County budget allocates 4 million dollars per year to the Maui Visitors Bureau to promote our "island lifestyle". CORA is an integral part of creating safe and enjoyable ocean experiences.

Devastating to Family owned businesses:

This astronomical fee hike will likely drive small family owned businesses out of business. This will mean that only large corporate sized operators will be able to enter the market. These corporate operators will then need to increase beach traffic and pay lower wages, in order to cover these higher costs. This outcome conflicts with everything that makes Maui unique and attractive for residents and visitors alike.

Small Businesses are the base of the economy:

When County puts the cost of doing business beyond the reach of small business, it kills the small businesses that make up the base of our island's economy. Small businesses are locally

owned and operated and keep their money circulating in our local economy. These operators are an inextricably linked to the local community. CORA schools are families, friends, and employers, that also spend their money and energies back into their local communities.

Lost Jobs and unemployment will outweigh all money collected:

The additional money collected from collecting higher CORA fees, will be easily offset by the inevitable layoffs and job losses. The community will be forced to bear the burden when the unemployed CORA workers eventually receive unemployment benefits.

Budget fallacy

It is a budgeting error to assume that County fee revenue will increase six-fold by raising the CORA fee six-fold. CORA family businesses simply cannot.

Betrayal of trust:

CORA operators have worked with the County for years or even decades and have fulfilled their obligations and requirements while providing jobs and vital services to the community. A sudden six-fold fee increase is an insult and is a betrayal of the hardworking and longstanding CORA community.

County risks disenfranchising the entire CORA community:

County actions like this could alienate and disenfranchise the entire CORA community, including dozens of CORA businesses, local families, hundreds of workers, and their dependents, and their supporting community.

SOLUTION:

Reset the CORA fees to \$500 per permit for this budget year and engage with the CORA community to address all concerns - budget, enforcement, growth, attrition, whatever they may be.



PUBLIC MEETING NOTICE

BUDGET AND FINANCE COMMITTEE

COUNCIL OF THE COUNTY OF MAUI

www.MauiCounty.us/BF

Committee Chair Riki Hokama

Committee Vice-Chair Mike White

Voting Members:
Gladys C. Baisa
Robert Carroll
Elle Cochran
Don Couch
Stacy Crivello
Don S. Guzman
Michael P. Victorino

Friday, May 15, 2015 1:30 p.m.

MEETING SITE:
Council Chamber
Kalana O Maui Building, 8th Floor
200 South High Street
Wailuku, Hawaii

2015 MAY -8 PM 12: 3U

AGENDA

PROPOSED FISCAL YEAR 2016 BUDGET FOR THE COUNTY OF MAUI (BF-1)

DESCRIPTION:

The Committee is in receipt of the following:

- 1. County Communication 15-41, from Council Chair Mike White, relating to the Fiscal Year 2016 Budget.
- 2. Correspondence dated May 7, 2015, from the Department of the Corporation Counsel, transmitting a proposed bill entitled "A BILL FOR AN ORDINANCE AMENDING TITLE 3, MAUI COUNTY CODE, ESTABLISHING A COUNTYWIDE SEWER REPLACEMENT CAPITAL IMPROVEMENT RESERVE FUND". The purpose of the proposed bill is to establish a countywide sewer replacement capital improvement reserve fund, pursuant to Section 9-14 of the Revised Charter of the County of Maui (1983), as amended, for the purpose of funding upgrades to the sewer and wastewater collection system and related improvements countywide.
- 3. Correspondence dated May 7, 2015, from the Department of the Corporation Counsel, transmitting a proposed bill entitled "A BILL FOR AN ORDINANCE AMENDING TITLE 3, MAUI COUNTY CODE, ESTABLISHING AN UPCOUNTRY WATER SYSTEM EXPANSION CAPITAL IMPROVEMENT RESERVE FUND". The purpose of the proposed bill is to establish an Upcountry water system expansion capital improvement reserve fund, pursuant to Section 9-14 of the Revised Charter of the County of Maui (1983), as amended, for the purpose of funding increased water system capacity Upcountry to address the long-standing water meter wait list in the area, and related improvements.

STATUS:

The Committee may consider whether to recommend passage of the proposed capital improvement reserve fund bills on first reading, with or without revisions, and other related action. No legislative action will be taken on any other aspects of the proposed Fiscal Year 2016 Budget.

ECONOMIC DEVELOPMENT REVOLVING FUND (BF-125)

DESCRIPTION:

The Committee is in receipt of County Communication 14-223, from the Economic Development Director, transmitting the following:

- 1. A proposed bill entitled "A BILL FOR AN ORDINANCE AMENDING APPENDIX A OF THE FISCAL YEAR 2015 BUDGET FOR THE COUNTY OF MAUI AS IT PERTAINS TO PART II, SPECIAL PURPOSE REVENUES - SCHEDULE OF REVOLVING/SPECIAL FUNDS FOR FISCAL YEAR 2015, ECONOMIC DEVELOPMENT REVOLVING FUND". The purpose of the proposed bill is to amend the Fiscal Year 2015 Budget to appropriate funds from the Economic Development Revolving Fund, pursuant to Chapter 3.81, Maui County Code, for the following: (1) Uptown Service, Inc. to renovate and convert its existing car wash facility to a full-service and take-out restaurant called "Da Car Wash Café", \$200,000; (2) Alpha, Inc. to purchase a National T-32 drill rig to offer lower-cost drilling to Maui deep-well projects, \$125,000; (3) Maui Innovation Group LLC, for the development of medical care management software to better manage patient care and comply with new Affordable Care Act regulations, \$175,000; (4) HNu Photonics, LLC, for infrastructure improvements and equipment acquisition for stem cell research, \$250,000; and (5) Aumakua Holdings Inc., to purchase equipment for a Maui Brewing Co. facility in Kihei to add new lines of beverages and increase exportation, \$250,000.
- 2. A report entitled, "Maui County Economic Development Revolving Fund (EDRF), First Round Grant Reviews, Report to the Mayor", dated August 10, 2014, recommending the five projects above, as selected by an investment committee.

STATUS:

The Committee may consider whether to recommend passage of the proposed bill on first reading, with or without revisions. The Committee may also consider other related action.

AMENDING FISCAL YEAR 2015 BUDGET: ECONOMIC DEVELOPMENT REVOLVING FUND (SEA LINK OF HAWAII, INC.) (BF-37)

DESCRIPTION:

The Committee is in receipt of County Communication 15-121, from the Budget Director, transmitting a proposed bill entitled "A BILL FOR AN ORDINANCE AMENDING APPENDIX A OF THE FISCAL YEAR 2015 BUDGET FOR THE COUNTY OF MAUI AS IT PERTAINS TO PART II, SPECIAL PURPOSE REVENUES – SCHEDULE OF REVOLVING/SPECIAL FUNDS FOR FISCAL YEAR 2015, ECONOMIC DEVELOPMENT REVOLVING FUND". The purpose of the proposed bill is to amend the Fiscal Year 2015 Budget to appropriate \$105,000 from the Economic Development Revolving Fund to Sea Link of Hawaii, Inc. to maintain operations of the Molokai Ferry, which provides a vital transportation link between the islands of Maui and Molokai.

STATUS:

The Committee may consider whether to recommend passage of the proposed bill on first reading, with or without revisions. The Committee may also consider the filing of County Communication 15-121 and other related action.

REMOTE TESTIMONY SITES				
Hana Council District Off Hana Community C 5091 Uakea Road Hana, Hawaii		ty Center 100 Ainoa Street Kaunakakai, Hawaii		
CONTACT INFORMATION	Office of Council Services 200 South High Street Wailuku, Hawaii 96793 www.MauiCounty.us/BF Committee Staff: Michele Yoshin	(808) 270-7838 (phone) (800) 272-0098 (toll-free from Lanai) (800) 272-0026 (toll-free from Molokai) (808) 270-7686 (fax) nura, Mark Pigao, and Yvette Bouthillier		
TESTIMONY	Oral or written testimony on any agenda item will be accepted. Each testifier shall be allowed to speak for three minutes on each item. For information on testifying please visit www.MauiCounty.us/how-to-testify or contact the Office of Council Services.			
DISABILITY ACCESS	People with disabilities requiring special accommodations should contact the Office of Council Services at least three working days prior to the meeting date.			
LIVE CABLECAST	Available on Akaku: Maui Community Media, Channel 53.			

AGENDA ITEMS ARE SUBJECT TO CANCELLATION.

bf:150515:mrp/mmy



CORA fee - last minute six-fold increase Patricia Cadiz

to:

tony, Dori Palcovich 05/19/2015 03:19 PM

Hide Details

From: Patricia Cadiz <patti@hstwindsurfing.com>

To: tony@rmasalesco.com, Dori Palcovich <dpalcovi@dbedt.hawaii.gov>

To: Small Business Regulatory Review Board

Aloha Tony and Dori,

Thank you for caring about our plight. It would be wonderful to have a letter from SBRRB stating your disapproval of the manner in which this six fold rate hike was handled (last minute and without reaching out to the stakeholders) as well as the seemingly cavalier and uninformed decision making on the matter.

Moments before deliberating our fee, when discussing a Security Alarm False Alarm Fee schedule, the Council quickly agreed to take 10 months to get feedback and then decide. We simply request the same curtesy. Especially because there is already other legislation and actions in the immediate pipeline that have potential to change the entire landscape for ocean activity guiding and lessons. The pending changes that we know about are:

- EAR 5 COMMERCIAL OCEAN RECREATIONAL ACTIVITY FEES, FINES, AND PENALTIES This sounds like it may be a fee re-structuring proposal. Perhaps % of gross? Per head?
- Councilman Hokama announced that he has a proposal for beach concessions (To replace CORA or compete with CORA?)
- State DLNR is in the process of reviewing applications for ocean access. State regulations need to be coordinated with County. State plans to charge 3% of gross or \$200/month, whichever is greater.

And the council deliberations revealed several misunderstandings of facts. Its irresponsible to make uninformed decisions. They seem to think that we do commercial activity in the parks which we do not. Our permits as really nothing more than beach access permits.

Please get the whole picture before making ill-advised changes.

Action was last minute, arbitrary and drastic... and unannounced.

Maui County is the first County in the State to tackle the management of ocean activity guiding and lessons. We're way ahead of others. Continue to refine - dont make reckless changes.

Our parks and activities are intrinsic to all that makes Maui No Ka Oi for activities. This deserves careful consideration.

As a comparison...

Downhill bike permit is only \$1,000 (How many lawsuits have downhill bike accidents caused? vs. How many have CORA prevented?)

CORA act as defacto lifeguards, supplementing Ocean Safety Officers by 5 or 6 fold.

CORA are not 'profiting off parks', in fact CORA guides and instructors are fulfilling the need for safe ocean experiences. Consider what would be the scenario without our services. (Atlas Shrugged)

Time is of the essence because the first reading of the Maui Budget is next Tuesday, May 26. That is our chance to offer testimony and hopefully see an amendment introduced and passed. June 5 is the final reading of the budget. So your letter should be submitted as testimony for the May 26 meeting pf the Maui County Council.

Mahalo and aloha,

Patricia B Cadiz 808-283-5070



CORA permit fee proposed increase suzanne dorn

to:

Dpalcovi 05/13/2015 10:41 PM

Hide Details

From: suzanne dorn <mauisportsunlimited@gmail.com>

To: Dpalcovi@dbedt.hawaii.gov

History: This message has been replied to.

Aloh Dori,

Below is a copy of an email that I sent to maui Council member Stacy Crivello, she is the only council person to return any calls or emails regarding the CORA fee increase. When I asked about the increase the only reason she gave me was "there are a lot of other people that want our permits" The proposed fee will raise my CORA annual. fees by \$20,000. This is not something I can afford and I will be forced to surrender some of my permits. I am a multi-sport business, offering surfing, windsurfing and kiteboarding at different beach locations.

Thank you Suzanne Dorn 808-280-7060

Aloha Council member Stacy Crivello,

thank you for the call back last Friday. You are the only council person to call us back (so far).

You mentioned that the motivation for the 600% increase is because "Other people want Permits". This seems to means that the proposed Price hike is a deliberate calculated tactic by the County to force us long term operators to abandon our permits.

The Number of Permits was capped in 2009 after the County parks EIS Study.

Permits have been already over issued, so even if many permits are abandoned they will not be allowed to be reissued, until numbers fall below the caps.

Example; 40 permits currently in use for Surfing, and they are capped at 13. So this means that 27 permits would need to be abandoned before one could be reissued.

This is forced attrition.

County is forcing our businesses to fail by artificially creating an economic disincentive.

It will undoubtedly also force small businesses out of business in favor of bigger businesses.

More Traffic at the parks:

This means that only the bigger businesses that can afford higher fees will stay in business, and there will be an economic imperative to recoup costs, so they must increase their beach traffic far above the current level of use, Increased use will put more pressure on the finite resources at the parks. The level of use was already quantified in the EIS. When the caps were set.

Undermining the EIS:

Forcing more operators to use this finite number of permits undermines the Purpose of the Study, by increasing beach traffic with the same number of permits.

All for the sake of paying a higher Permit fees.

The harm does not outweigh the benefits:

Is the Council really going to force 70 percent of Surf operators to go out of business just to make room for One (1) new person?

Why kill respectable Businesses?

These small businesses are established, law abiding, rule compliant, insured, experienced, trained, tax paying members of the community. They are also employers with a work force, that depends on these jobs to feed their families. Is county going to send them to the unemployment line

Please reconsider the Fee Hike,

It will do way more harm than good. It is unfair to small businesses, and it is unfair to the workers that will lose their jobs and the income needed to support their families. It will ultimately cost the State economy much more in unemployment benefits paid out as small businesses close and many workers lose their jobs.

Regards,

Suzanne Dorn

(808) 280-7060

www.mauisportsunlimited.com

808-280-7060

visit us at our south shore center surf and paddleboard shop Surf Club Maui 22 Alahele Street, Kihei Hawaii 96753 www.surfclubmaui.com



Skype?
Patricia Cadiz
to:
Dori Palcovich
05/13/2015 11:18 PM
Hide Details
From: Patricia Cadiz <patti@hstwindsurfing.com>
To: Dori Palcovich <dpalcovi@dbedt.hawaii.gov>

Aloha Dori,

Everything is happening so quickly that I start one summary and then there is an update... As of today, we have pledge of support from three council members. More calls to be made tomorrow.

Also, Pap Tumpap has pledged her support and worked all day on CORA. I've made contact with Lisa Paulson from MH&L and she is aware and is working with Toni Davis on this for us. Feeling much better as of today.

CORA has been lapse in staying connected with the new Council members. We are very misunderstood and its our own fault. This has been a bit of a wake up call to all that we need to be more pro-active in the future.

Regarding the May 20 meeting... we are wondering if we could possibly Skype in to answer any questions of the Board - as opposed to sending a delegate.

Mahalo,
Patti Cadiz
HST Windsurfing, Surfing, SUP and Kitesurfing School
425 Koloa Street, Kahului, Maui
(inside Hi-Tech Surf Sports)
www.hstwindsurfing.com
www.hstkitesurfing.com
1-800-YOU-JIBE (968-5423)
808-871-5423



Fwd: CORA permit fee

Patricia Cadiz

to:

Dori Palcovich

05/19/2015 11:29 AM

Hide Details

From: Patricia Cadiz <patri@hstwindsurfing.com>
To: Dori Palcovich <dpalcovi@dbedt.hawaii.gov>

History: This message has been forwarded.

Aloha Dori,

Thank you so much for your support. Here is the letter that I sent to Mike White.

Here are the council members that will not meet with us or talk to us: Mike White, Riki Hokama, Gladys Baisa, Don Guzman.

I have been line to line all morning but calling Tony right this minute!

Aloha, Patti

Begin forwarded message:

From: Patricia Cadiz <pbc5@mac.com>

Subject: CORA permit fee

Date: May 18, 2015 at 12:12:23 AM HST

To: Councilmember Mike White < Mike. White@mauicounty.us >

Aloha Councilman White,

Thank you for listening to my testimony and those of my peers last Friday, May 15, 2015. We did not want to take too much of your time so we deliberately minimized our collective speaking time. This weekend, we were able to find the broadcast of the May 4th Committee meeting when the CORA fee hike was discussed and passed.

I have always respected your approach and business acumen as well as your tendency to run a 'tight ship' with reasonable frugality. But I have to admit I was very surprised to hear some of your testimony. There are several issues that are misunderstood. We would appreciate the opportunity to meet with you this week to explain each of these points further.

1. CORA did not "Buy Up" permits

If you read my husband's email of May 6, you may now appreciate that we did not go out and "buy up" a lot of permits. Alan wrote:

"I am one (1) business. I started with one permit. When the county revised the ordinance in 2005, ... my one permit became three permits because I offer three activities. Then, Director Horcajo expanded that to charge per park AND per activity. Therefore the number of permits I needed jumped to 9 because I listed four parks.

I don't use all those parks at the same time though; 90% of my business is in one park providing two activities. The other permits I hold so that I can offer alternate locations when conditions are unsafe at my primary location. Off shore wind, polluted-runoff from the spillway, shark incidents, high surf, too much wind, too little wind, all challenge us to provide safe and enjoyable

lessons."

Nor are we hoarding permits that we do not use. We *do* need all the permits we have to survive the windless winter months.

The 'caps' were set in part by asking all existing businesses, where we went and what we do. Right from the beginning we explained that we have "alternate sites" to help us survive through the windless winters. We never represented that we use each park all day every day. Yet a permit had to be issued even for minimal use. Parks wanted to know where we were going and what we were doing. Parks definitely did not instruct us to maximize the commercial activity in each park. In fact, since 2002 there has been plenty pressure to reduce our presence in the parks.

2. CORA are not hoarding permits

As I mentioned in my testimony, I am keenly aware that there are newcomers who want permits - especially for surfing at Ukumehame Beach Park. The cap is set at two surf permits at Ukumehame. Presently CORA collectively hold 8 permits for surfing there - but its not overrun with activity because most of us use it as an alternate location. Seven schools would have to give up their permits before Parks would consider issuing a permit to a new comer there. That's \$3500 in permit fees now versus \$3000 to a new operator who will probably have a far greater impact on the regulars there. There are other obvious reasons that favor the status quo and I'd like the opportunity to share them with you in person.

3. How much of the enforcement budget is appropriately allocated to CORA?

I'd also like to offer some information about the expense side of CORA. Enforcement officers have issued over 400 citations for illegal camping and, as far as I know, zero for CORA. Our fees are supposed to be spent on CORA related expenses only. With only 37 businesses and no known citations, how much of the enforcement budget is appropriately allocated to CORA? Probably less than the \$62,700 when the fee is at \$500 and certainly less than \$350,000 per Council's budget. In actuality, most enforcement expense and effort is for illegal camping. I have more information on this that I'd like to share at a meeting too.

I certainly appreciate enforcement challenges and frustrations but I am certain effective enforcement is not only possible, it is not expensive. I have a meeting on June 2 with Parks Director and Deputy Director to share some ideas for improving enforcement success on renegade operators as well as the sub-leting problem that you mentioned. My suggestions are from the expertise of an experienced enforcement official in a comparable challenge.

4. A CORA Beach Access Permit is Nothing like a Beachfront Commercial Kiosk or Manele Small Boat Harbor on Lanai

Our permits are nothing more than beach access permits and are NOTHING like Manele Harbor or Kaanapali Beach. CORA service providers are not allowed to do any commercial activity in the parks. Rules dictate that we have a 30 minute limit to unload, outfit our guests, and move to the water. We are not even allowed to use Parks water supply. We provide the necessary guiding and training services that the County cannot provide in-house. There is no "show-casing" or solicitation allowed in the Park. CORA Rules limit the number of guests we may have each day as well as the days of the week, times, holidays and special events. We have 42 pages of rules. But, all CORA instructors are CPR and First Aid certified. On a daily basis our knowledge is shared to make experiences safer. This is an unacknowledged benefit to the County and has undoubtedly saved the County millions of dollars in lawsuits for "failure to warn", as has happened in the past. A true cost-benefit analysis would reveal that the County is actually getting a pretty sweet deal from its CORA partners.

5. CORA permits are not commodities

Nor is there a fair comparison to the small boat harbor slip and selling prices of \$400-500,000. CORA is not a racket. The services that we provide are too specialized and require dedicated experts. CORA service providers are small, family owned business with a lot of challenges. Many of those challenges are out of our control - like the weather. It is a fallacy that we are all making buckets of money. And its a fallacy that our little struggling businesses are holding these permits for long term gains like the harbor slips. In fact, the number of CORA permits has gone DOWN from 352 in 2008 to 118 in 2014. If they are so valuable, why are so many being abandoned?

Please also consider that:

- A higher fee penalizes the legal operators.
- A higher fee encourages more renegades and more sub-letting of permits.
- CORA only manages 6 SKILLS (Kayaking, Kitesurfing, Scuba, Snorkeling, Surfing and Windsurfing.)
- CORA does NOT include the Kaanapali ACTIVITIES, that Councilwoman Cochran mentioned, of jet skiing, parasailing, banana boating and wake boarding.
- Higher fees actually incentivize more commercial activity perhaps even exceeding the carrying capacity.

When the CORA ordinance was discussed back in 2003, we explained that each park and each activity were so unique that they could not be managed with a One-Size-Fits-All ordinance. That is why the director was given authority to write Administrative Rules. You can make the same argument here. A One-Giant-Fee policy punishes the smallest operators as well as the operators that need diversity to survive.

It sounds like there are ordinance changes pending from Parks as well as an RFP proposal from Councilman Hokama. So plenty changes coming down the pipeline -but none have been properly vetted. Our parks are vitally important to both residents and visitors alike. Please reset the fee before irreparable damage is done to these small businesses. Please do not make this mistake as it will have many, many negative unintended consequences.

In closing, as constituents from your district, as supporters of your campaigns, as a 30 year business who's viability is at stake, may we meet with you *this week*, please?

Thanking you in advance,

Patricia Cadiz HST Windsurfing, Surfing and Kitesurfing Lessons 808-283-5070



ABOUT CORA PERMIT FEES 2015

Action Sports

to:

don.couch, Don.Guzman, Robert.Carroll, Gladys Baisa, Elle.Cochran, Stacy.Crivello, michael.victorino, Riki.Hokama, mike.white 05/19/2015 11:23 AM

Cc:

"mayors.office", kaala.buenconsejo, pamela, dpalcovi, John Buck, Keith Regan Hide Details

From: Action Sports <actionsportsmaui@gmail.com> Sort List...
To: don.couch@mauicounty.us, Don.Guzman@mauicounty.us,

Robert.Carroll@mauicounty.us, Gladys Baisa <gladys.baisa@mauicounty.us>,

Elle.Cochran@mauicounty.us, Stacy.Crivello@mauicounty.us,

michael.victorino@mauicounty.us, Riki.Hokama@mauicounty.us,

mike.white@mauicounty.us

Cc: "mayors.office" <mayors.office@co.maui.hi.us>, kaala.buenconsejo@co.maui.hi.us, pamela@mauichamber.com, dpalcovi@dbedt.hawaii.gov, John Buck

<John.Buck@co.maui.hi.us>, Keith Regan <keith.regan@mauicounty.gov>

Please respond to fun@actionsportsmaui.com

History: This message has been forwarded.

1 Attachment



cora-expenses-expenditure-sheet.jpg

ABOUT CORA PERMIT FEES 2015

Tuesday, May 19, 2015

Dear Council members,

Please take into consideration the following information when deliberating about setting CORA permit Fees in the upcoming budget meeting.

CORA Money not Spent on CORA ADMIN/Enforcement:

The money collected from CORA for permit fees was meant to cover the admin costs, and later for enforcement. CORA Fees are now being diverted to Non-CORA use. To things like sand replenishment for storm damage to non-CORA parks, and many other non-CORA related expenses.

The original CORA permit Fee:

Our oldest CORA members remember the promulgation of the first CORA permits. The original fee was proposed at \$5 dollars, like a bicycle fee, but initially set at \$50 dollars.

The permit fee is a Admin fee not a User fee:

The CORA Permit fee is an admin fee, to offset the costs of admin the system. It was never intended to be a user fee.

Use of Parks varies:

Park use differs widely between different operators, the size businesses, and types of activities, and weather. Some small businesses use parks a few days per week, and use is very limited. Other users are larger with one location that have more use. These uses differ greatly. Any user based fee would have to take into consideration the small operators too.

Some parks have many usage restrictions:

Some parks can only be used some of the time. Weather suitability, physical orientation, geography, other user groups, CORA activity type, and site-specific rules, limit a site's availability and efficacy.

Parks permit fees Increase Unfair to smaller operators:

The 3000 dollar (600%) fee increase in totally unfair to smaller infrequent users, and to small more diverse operators with several permits for alternate sites or multiple activities. Even a 100% increase from current fees is unfair to small operators, and would be overly burdensome and create significant hardship.

Permits are necessary for survival:

The CORA permit is a vital part of any CORA business.

They simply cannot access the beach without these permits. This gives the power of life and death of these operators into the hands of the parks Dept, and the Budget committee. Budget committee should set a fair price that allows these law abiding businesses to continue. It is a Councilperson's Kuleana to get to know the needs of the CORA and not to wipe them out with heavy handed and under-informed decisions.

Please do not mess with the CORA permit fee.

Without these permits CORA cannot continue. Radical changes in fees and arbitrary or speculative restructuring can and will have a devastating effect on these operators and could put them out of business. Please keep the fees the same as they are now, until we have had a chance to contribute to the discussion that so profoundly affects our livelihoods, our community, and our future.

Regards,

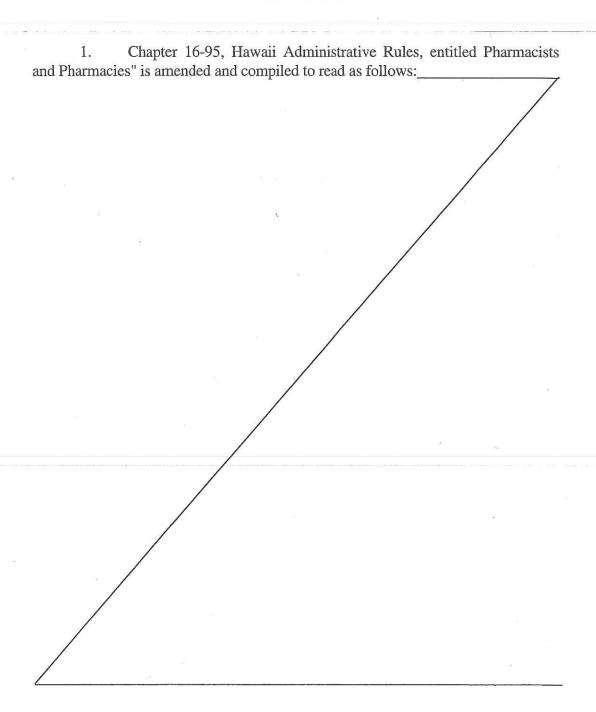
David Dorn

^{*}See attached CORA expenditure sheet.

Exhibit 1

DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS

Amendment and Compilation of Chapter 16-95 Hawaii Administrative Rules



HAWAII ADMINISTRATIVE RULES

TITLE 16

DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS

CHAPTER 95

PHARMACISTS AND PHARMACIES

Subchapter 1 General Provisions

· ·	
§16-95-1	Objective; scope
§16-95-2	Definitions
§16-95-3	Repealed
§16-95-4	Repealed
§16-95-5	Repealed
§16-95-6	Repealed
§16-95-7	Repealed
§16-95-8	Repealed
§16-95-9	Repealed
§16-95-10	Repealed
§16-95-11	Repealed
§16-95-12	Repealed
§16-95-13	Repealed
§16-95-14	Display of license or permit
§16-95-15	Repealed
§16-95-16	Repealed
§16-95-17	Repealed
§16-95-18	License or permit required
§16-95-19	License or permit nontransferable

Subchapter 2 Applications

§16-95-21	Forms, docur	nentat	ion, and notifica	ation			
§16-95-22	Application	and	requirements	for	pharmacist	license	by
98	examinati	ion					
§16-95-22.5	Application a	ind rec	quirements for p	harma	acist license b	y reciproc	city
§16-95-23	Temporary lie	cense					

§16-95-24	Pharmacy intern permit
§16-95-25	Repealed
§16-95-26	Pharmacy permit
§16-95-27	Repealed
§16-95-28	Repealed
§16-95-29	Repealed
§16-95-30	Wholesale prescription drug distributor license requirements
§16-95-31	Miscellaneous permit
§16-95-32	Criminal conviction
§16-95-32.2	Denial or rejection of application

Subchapter 3 Education and Experience Documentation

§16-95-33	Education documentation for a pharmacist license
§16-95-33.2	Education documentation for a pharmacy intern permit
§16-95-34	Experience verification for a pharmacist by examination
§16-95 - 35	Repealed
§16-95-36	Experience verification for a pharmacist licensed by reciprocity or
	temporary pharmacist license

Subchapter 4 Repealed

§16-95-39	Repealed
§16-95-40	Repealed
§16-95-41	Repealed
§16-95-42	Repealed
§16-95-43	Repealed

Subchapter 5 Repealed

§16-95-44	Repealed
§16-95-45	Repealed
§16-95-46	Repealed
§16-95-47	Repealed
§16-95-48	Repealed
§16-95-49	Repealed
§16-95-50	Repealed

Subchapter 6 Repealed

§16-95-51	Repealed
§16-95-52	Repealed
§16-95-53	Repealed
§16-95-54	Repealed

Subchapter 7 Repealed

§16-95-55	Repealed
§16-95-56	Repealed
§16-95-57	Repealed
§16-95-58	Repealed
§16-95-59	Repealed
§16-95-60	Repealed
§16-95-61	Repealed
§16-95-62	Repealed
§16-95-63	Repealed
§16-95-64	Repealed

Subchapter 8 Repealed

§16-95-65 Repealed

Subchapter 9 Renewal

§16-95-70	Notice of renewal
§16-95-71	Date for filing
§16-95-72	Automatic forfeiture for failing to renew
§16-95-73	Restoration of forfeited license or permit
§16-95-74	Board may refuse to renew a license or permit

Subchapter 10 Scope of Practice

§16-95-79	Supervision by a registered pharmacist
§16-95-80	Physical presence of a registered pharmacist
§16-95-81	Emergency kits
§16-95-82	Valid prescriptions
§16-95-83	Substitution; drug product selection
§16-95-84	Transfer of prescriptions
§16-95-85	Scope of practice of a pharmacy intern
§16-95-86	Scope of practice of a pharmacy technician

§16-95-87 Return or exchange of drugs prohibited Subchapter 11 Record Keeping Requirements §16-95-93 Records of dispensing §16-95-94 Automated data processing systems §16-95-95 Security of records §16-95-96 Record keeping for wholesale prescription drug distributors Subchapter 12 Advertising Practices §16-95-101 Procedures to advertise prescription drugs Procedures to advertise related pharmacy services §16-95-102 §16-95-103 Advertising of controlled substances prohibited Subchapter 13 Disciplinary Sanctions, Application Denial, Hearings, Administrative Practice and Procedure §16-95-110 Grounds for revocation, suspension, refusal to renew or restore, denial, or conditioning of license or permit §16-95-111 Denial

Demand for hearing; proceedings upon demand for hearing

Subchapter 14 Oral Testimony

§16-95-118 Oral testimony

§16-95-112

§16-95-113

Subchapter 15 Fees

§16-95-123	Fees established
§16-95-124	
§16-95-125	Dishonored checks considered failure to meet requirements

Administrative practice and procedure

Subchapter 16 Emergency Contraception Collaborative Agreement

§16-95-130 Emergency contraception written collaborative agreement

SUBCHAPTER 1

GENERAL PROVISIONS

§16-95-1 Objective; scope. This chapter is intended to clarify and implement chapter 461, Hawaii Revised Statutes, to the end that the provisions thereunder may be best effectuated and the public interest and welfare most effectively served and protected. Other requirements of state or federal law, including the laws enforced by the state department of health and department of public safety, which also may be applicable to the practice of pharmacy or to licensees or permittees under chapter 461 Hawaii Revised Statutes, are not encompassed within the scope of this chapter. [Eff 5/16/64; am and ren §16-95-1, 6/22/81; am and comp 12/24/92; comp 12/25/04; comp] (Auth: HRS §461-4.5) (Imp: HRS §461-4.5)

§16-95-2 <u>Definitions.</u> As used in this chapter unless the context clearly indicates otherwise:

"ACPE" means the Accreditation Council for Pharmacy Education, formerly known as the American Council on Pharmaceutical Education, which is the national agency for the accreditation of professional degree programs in pharmacy and providers of continuing pharmacy education.

"Automated data processing system" or "ADP system" means a system utilizing computer software and hardware for the purpose of record keeping.

"Board" means the board of pharmacy.

"BREG" means the business registration division of the department.

"Department" means the department of commerce and consumer affairs.

"Director" means the director of commerce and consumer affairs.

"Dispense" or "dispensing" means the furnishing of drugs pursuant to a prescription in a suitable container, appropriately labeled for subsequent administration to, or use by, a patient or other individual entitled to receive the drug.

"HRS" means the Hawaii Revised Statutes.

"Immediate supervision" means that a registered pharmacist is physically present in the area or location[,] where a pharmacy intern or pharmacy technician is working and [performs a final assessment of each ingredient and quantity used and the prescription label to insure the correctness and accuracy thereof.] oversees the correctness and accuracy of the prescription's ingredients, quantity, and label.

"Institutional facility" includes a:

(1) Hospital;

- (2) Convalescent home;
- (3) Nursing home;
- (4) Extended care facility;
- (5) Mental institution;
- (6) Rehabilitation center;
- (7) Health maintenance organization;
- (8) Psychiatric center;
- (9) Mental retardation center;
- (10) Penal institution; or
- (11) Any other organization whose primary purpose is to provide a physical environment for patients to obtain health care services or at-home care services, except those places where physicians, dentists, veterinarians, osteopaths, podiatrists, or other prescribers who are duly licensed, engage in private practice.

"Institutional pharmacy" means a pharmacy providing services to an institutional facility

"NABPLEX" means the National Association of Boards of Pharmacy Licensure Examination, now known as the NAPLEX.

"NAPLEX" means the North American Pharmacist Licensure Examination, previously known as the NABPLEX.

"Partnership" means a general partnership, a limited partnership, a limited liability partnership, or a limited liability limited partnership.

["Pharmacist assistant"] "Pharmacy intern" means a student or graduate of a school or college of pharmacy, that is accredited or is a candidate for accreditation by the ACPE, and who is issued a permit by the board to work under the immediate supervision of a registered pharmacist.

"Pharmacy technician" means a nonlicensed individual, other than a pharmacy [assistant,] <u>intern</u>, who assists the pharmacist in various activities under the immediate supervision of a registered pharmacist.

["Prescriber" means a licensed practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine, holding a current and valid license by the proper authority to prescribe drugs.

"Prescription" means a written, facsimile, or telephone order from a prescriber for dispensation of a drug. A telephone order from a prescriber or the prescriber's authorized agent, shall only be valid if the order is immediately reduced to writing by the pharmacist. Prescription also includes an order written in the chart of a patient in an institutional facility by a prescriber.]

"Wholesale distribution" means the [distribution] <u>transfer</u> of prescription drugs to persons other than a consumer or patient, but does not include:

- (1) Intracompany sales, defined as any transaction or transfer between an entity and any division, subsidiary, parent, or affiliated or related company under common ownership and control;
- (2) The purchase or other acquisition, by [hospital or other health care entity] an institutional facility that is a member of a group purchasing organization, of a drug for use by the entity's [own use,] patient, from the group purchasing organization or from other [hospitals or health care entities] institutional facilities that are members of the group purchasing organization;
- (3) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1986, as amended, to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
- (4) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among [hospitals or other health care entities] institutional facilities that are under common control[; for]. For purposes of this [section,] paragraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, working rights by contract, or otherwise;
- (5) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons[; for]. For purposes of this [section,] paragraph, "emergency medical reasons" includes, but is not limited to, transfers of prescription drugs by a [retail] pharmacy to another [retail] pharmacy to alleviate a temporary shortage, except that the gross dollar value of such transfers shall not exceed five [percent] per cent of the total prescription drug sales revenue of either the transferor or transferee pharmacy during any period of twelve consecutive months;
- (6) The sale, purchase, or trade of a drug, or an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;
- (7) The distribution of drug samples by manufacturers' representatives or distributors' representatives. For purposes of this [section,] <u>paragraph</u>, "drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug; or
- (8) The sale, purchase, or trade of blood and blood components intended for transfusion. For purposes of this [section,] paragraph,

"blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing; and "blood component" means that part of blood separated by physical or mechanical means.

"Wholesale distributor" means any person or entity in this State engaged [in wholesale distribution of prescription drugs,] in the transfer of prescription drugs to a person other than a consumer or patient, including, but not limited to, manufacturers; repackers; own label distributors; private label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; prescription drug repackagers; [physicians; dentists; veterinarians;] practitioners; birth control and other clinics; individuals; hospitals; nursing homes and their providers; health maintenance organizations and other health care providers; and retail and hospital pharmacies that conduct wholesale distributions. The term "wholesale distributor" shall not include any carrier for hire or person or entity hired solely to transport prescription drugs. For purposes of this [section,] definition, "manufacturer" means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug; and "prescription drug" means any human drug required by federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act. [Eff 5/16/64; am 8/7/70; am and ren §16-95-2, 6/22/81; am and comp 12/24/92; comp 12/25/04;] (Auth: HRS §461-4.5) (Imp: HRS §461-4.5) am and comp

§16-95-3 Repealed. [R 12/24/92]

§16-95-4 Repealed. [R 12/24/92]

§16-95-5 Repealed. [R 12/24/92]

§16-95-6 Repealed. [R 12/24/92]

§16-95-7 Repealed. [R 12/24/92]

§16-95-8 Repealed. [R 12/24/92]

§16-95-9 Repealed. [R 12/24/92]

§16-95-10 Repealed. [R 12/24/92]

§16-95-11 Repealed. [R 12/24/92]

§16-95-12 Repealed. [R 12/24/92]

§16-95-13 Repealed. [R 12/24/92]

§16-95-14 <u>Display of license or permit.</u> [The license or permit, together with evidence of current validation, shall be conspicuously displayed in the place of business and the holder of a license] <u>The holder of a license or permit shall conspicuously display, in the place of business, that license or permit and shall have the [holder's license or] evidence of current validation in the holder's possession at all times[, provided that a relief pharmacist shall not be required to display a license or permit]. [Eff 5/16/64; am and ren §16-95-14, 6/22/81; am and comp 12/24/92; comp 12/25/04; am and comp] (Auth: HRS §§461-4, 461-9, 461-16)</u>

§16-95-15 Repealed. [R 12/24/92]

§16-95-16 Repealed. [R 12/24/92]

§16-95-17 Repealed. [R 12/24/92]

§16-95-18 <u>License or permit required.</u> It shall be unlawful for a person who is not licensed or who has not been issued a permit under chapter 461, HRS,

and this chapter to engage in the practice of a pharmacist, to perform the duties of a [pharmacist assistant,] <u>pharmacy intern</u>, to operate a pharmacy, to engage in the wholesale distribution of drugs, or to engage in any activities requiring a miscellaneous permit. [Eff and comp 12/24/92; comp 12/25/04; am and comp] (Auth: HRS §461-4.5) (Imp: HRS §461-4.5, 461-10)

§16-95-19 <u>License or permit nontransferable</u>. Any license or permit issued by the board shall be valid only [in the name] for the person to which it is issued and shall not be transferable. [Eff and comp 12/24/92; comp 12/25/04; am and comp

] (Auth: HRS §461-4.5) (Imp: HRS §461-4.5)

SUBCHAPTER 2

APPLICATIONS

§16-95-21 Forms, documentation, and notification. (a) An application for license or permit shall be made under oath on forms provided by the board and shall not be considered complete unless accompanied with the required documentation and fees. It shall be each applicant's responsibility to furnish all information and any documentation requested by the board.

- (b) The application form may require the applicant and any personnel of the applicant to provide the following:
 - (1) The applicant's full name;
 - (2) A statement that the applicant has attained the age of majority;
 - (3) The applicant's current business or mailing address for publication, and the applicant's current residence address;
 - (4) The applicant's social security number;
 - (5) The applicant's educational history and evidence of the education;
 - (6) The date and place of any conviction of a crime directly related to the practice of pharmacy, drugs, drug samples, wholesale or retail drug distribution, or distribution of controlled substances, unless the conviction has been expunged or annulled or is otherwise precluded from consideration by section 831-3.1, HRS;
 - (7) The [state(s)] <u>state or states</u> or United States territory in which the applicant is currently licensed, and any information regarding any disciplinary proceedings pending or disciplinary actions taken by any state or jurisdiction against the license;
 - [(8) A photograph of the applicant for identification purposes;

- (9)] (8) A statement that the applicant is a United States citizen or an alien authorized to work in the United States;
- [(10)] (9) The names, addresses, phone numbers, and social security numbers of corporate officers or partners or other personnel of the applicant;
- [(11)] (10) Verification that the corporation, partnership, or entity is properly registered with [the business registration division of the department of commerce and consumer affairs] BREG;
- [(12)] (11) Verification that the trade name, if any, is properly registered with [the business registration division of the department of commerce and consumer affairs] BREG;
- [(13)] (12) The name and license number of the pharmacist in charge of the prescription area and the [name(s)] <u>name or names</u> and license [number(s)] <u>number or numbers</u> of any other pharmacists employed;
- [(14)] (13) The name, position, and title of any person responsible for the distribution of drugs; and
- [(15)] (14) Any other information the board may require to investigate the applicant's qualifications for license or permit.
- (c) Any requirement that the board provide notice to licensees or permittees shall be deemed met if notice is sent to the address on file with the board.
- (d) Any change in the application or of any information filed with the board shall be reported to the board, in writing, within ten days of the change.
- (e) Upon closure of a pharmacy located in this State, the pharmacy shall:
 - (1) Provide written notice to the board within ten days;
- (2) <u>Return all indicia of licensure.</u> [Eff 5/16/64; am and ren §16-95-21, 6/22/81; am and comp 12/24/92; comp 12/25/04; am and comp] (Auth: HRS §461-4.5) (Imp: HRS §8461-4.5, 461-5, 461-6, 461-7, 461-8.6, 461-14, 461-15)

Historical note: The substance of this section is based in part upon sections 16-95-13 and 16-95-35. [Eff 5/12/64; am and ren §§16-95-13, 16-95-35, 6/22/81; R 12/24/92]

§16-95-22 <u>Application and requirements for pharmacist license by examination.</u> (a) An application for license by examination shall [be filed at least sixty days before the examination date and must] be accompanied by the required application fee, which shall not be refunded, and [by] the examination fee. An

examination fee may be refunded provided a written request for refund is made prior to the application deadline.

- (b) An applicant shall:
- (1) Have attained the age of majority; and
- (2) Hold a degree from a school or college of pharmacy which has received candidate status with or has been accredited by the [American Council on Pharmaceutical Education (ACPE);] ACPE;
- (c) For issuance of the license, the applicant shall provide evidence of:
- (1) At least [two thousand] <u>fifteen hundred</u> hours of practical experience; and
- (2) Passage of either the [National Association of Boards of Pharmacy Licensing Examination (NABPLEX), the Federal Drug Law Examination (FDLE), and a state jurisprudence examination by a passing score of at least seventy-five points.] NABPLEX or the NAPLEX, and the Hawaii Multistate Pharmacy Jurisprudence Examination (MPJE). The MPJE requires a passing score of at least seventy-five points.
- (d) An applicant who is a participant in the National Association of Boards of [Pharmacy] Pharmacy's (NABP) score transfer program shall be responsible for having the score report sent to the board.
- (e) A foreign graduate, in addition to the <u>requirements</u> above and in lieu of the candidacy or accreditation requirements by the ACPE in (b)(2), shall provide verification of passing the following:
 - (1) The Foreign Pharmacy Graduate Equivalency Examination (FPGEE); and
 - (2) The Test of English as a Foreign Language (TOEFL);[and
 - (3) The Test of Spoken English (TSE)]. [Eff 5/16/64; am 3/16/80; am and ren \$16-95-22, 6/22/81; am and comp 12/24/92; comp 12/25/04: am and comp] (Auth: HRS §461-4.5) (Imp: HRS §\$461-5, 461-6)
- §16-95-22.5 Application and requirements for pharmacist license by reciprocity. (a) An application for license by reciprocity shall be filed on forms provided by the board. The applicant shall submit:
 - (1) Evidence of current and valid licensure to practice pharmacy in another state or jurisdiction with qualifications which equal or exceed those of this State;

- (2) Information regarding any disciplinary action taken or any [unresolved] complaints or investigations pending against the applicant;
- (3) Evidence of having practiced for at least [two thousand] <u>fifteen</u> <u>hundred</u> hours as a licensed pharmacist within the five years preceding the date of application; and
- (4) A completed official NABP licensure transfer application within ninety days from the date of issuance by the NABP, unless extended by the NABP.
- (b) The board shall not issue a license by reciprocity unless the other state or jurisdiction grants reciprocal licensure to this state's licensees.
- (c) The board may deny licensure by reciprocity if the applicant <u>fails</u> to <u>fulfill the requirements herein or</u> has had any disciplinary action taken or if any [unresolved] complaints are pending. [Eff and comp 12/24/92; comp 12/25/04; am and comp] (Auth: HRS §461-4.5) (Imp: HRS §461-8.5)
- §16-95-23 <u>Temporary license</u>. (a) An application for temporary license may be filed at the same time as an application for examination and shall be accompanied by the [required] <u>non-refundable</u> application fee [which shall not be refunded and an examination fee]. Following a determination by the board that the qualifications for admission to the examinations listed in <u>section</u> 461-6, <u>Hawaii Revised Statutes</u> exist, a temporary license to practice pharmacy may be issued, provided the applicant:
 - (1) Passes the [state jurisprudence examination with a score of not less than seventy-five points;] <u>Hawaii MPJE with a score of at least seventy-five points;</u>
 - (2) Submits [a photocopy] a verification, by an official of the licensing authority of that other state or territory of the United States, of a current and valid license to practice pharmacy in the other state or [jurisdiction] territory of the United States and
 - (3) Submits evidence that the applicant has practiced for at least [two thousand] <u>fifteen hundred</u> hours as a licensed pharmacist within the five years preceding the date of application.
- (b) The temporary license shall be valid only until the results of the next administration of the NABPLEX [and FDLE] or the NAPLEX examinations are received by the board.
- (c) In the event the pharmacist fails to take and pass [the examinations] either the NABPLEX or NAPLEX examination, the temporary license may be extended, for good and just cause, provided a request for extension

is made in writing. In no case shall the temporary license be extended beyond three consecutive administrations of the examinations. [Eff 5/16/64; am 3/16/80; am and ren §16-95-23, 6/22/81; am and comp 12/24/92; comp 12/25/04; am and comp

] (Auth: HRS §§461-4.5, 461-7) (Imp: HRS §§461-4.5, 461-7)

- §16-95-24 [Pharmacist assistant permit] Pharmacy intern permit (a) An application for a permit to work as [an assistant to a pharmacist] a pharmacy intern may be filed at any time. The board may delegate to the board's executive [secretary] officer the authority to issue a [pharmacist assistant] pharmacy intern permit to qualified applicants.
- (b) An applicant shall provide verification that the applicant has satisfactorily completed at least one year of instruction in a college of pharmacy and is currently enrolled in or is a graduate of a college of pharmacy which has received candidate status with or has been accredited by the ACPE.
- (c) A copy of the applicant's diploma, [or] <u>an</u> official transcript showing the date of graduation, or a letter from the dean or registrar that the applicant has completed the first year of school at a college of pharmacy shall be submitted with the application.
- (d) The applicant shall provide the name and license number of the supervising pharmacist and the name and address of the pharmacy at which the applicant is employed or will be employed. [Eff 5/16/64; am and ren §16-95-24, 6/22/81; am and comp 12/24/92; comp 12/25/04; am and comp] (Auth: HRS §461-4.5) (Imp: HRS §\$461-4.5, 461-9)

<u>Historical note:</u> The substance of this section is based substantially upon sections 16-95-44 and 16-95-45. [Eff 5/16/64; am 8/7/70; am 6/11/77; am and ren §§16-95-44, 16-95-45, 6/22/81; R 12/24/92]

§16-95-25 Repealed. [R 12/24/92]

- §16-95-26 <u>Pharmacy permit.</u> (a) An application for a pharmacy permit shall be filed in duplicate at least fifteen days before a board meeting and must be accompanied by the application fee which shall not be refunded.
 - (b) The application shall include:
 - (1) A floor plan of the prescription area which shall diagram the space and location of fixtures such as counters, tables, drawers, shelves,

- storage cabinets including a locked cabinet, library, sink with hot and cold water, proper sewage outlet, and refrigeration storage equipment;
- [(2) The date the pharmacy will be ready for inspection;
- (3)] (2) The name and license number of the pharmacist in charge and any other pharmacists employed;
- [(4)] (3) A letter of verification or bill of sale that the pharmacy has been bought with the effective date of sale if the pharmacy was purchased;
- [(5)] (4) Evidence that the entity is currently registered with [the business registration division (BREG), department of commerce and consumer affairs] BREG. If a corporation [or], partnership, or limited liability company has been registered for more than one year, a "Certificate of Good Standing" [or "Certificate of Qualification"] from the department shall be attached. If a corporation [or], partnership, or limited liability company has been registered for less than one year, a "file-stamped" copy of the document filed with BREG shall be attached; [and]
- [(6)] (5) Evidence that the trade name, if any, is properly registered with [the business registration division, department of commerce and consumer affairs.] BREG;
 - (6) An attestation that, at a minimum, the pharmacy possess or has electronic access to the following reference materials:
- [(c) A permit shall not be issued prior to an inspection report by the regulated industries complaints office (RICO) of the department of commerce and consumer affairs which indicates that the applicant has the minimum reference materials and technical clinical equipment and supplies.
 - (1) The minimum reference materials that a pharmacy shall possess are as follows:]
 - (A) United States Pharmacopeia National Formulary, and all supplements;
 - (B) [Federal Drug Enforcement Agency Regulations;] <u>Federal Drug Enforcement Administration regulations</u>;
 - (C) State uniform controlled substances laws, [Hawaii Revised Statutes,] chapter 329 <u>HRS.</u> [, and Hawaii Administrative Rules, chapter 11-32];
 - (D) State food and drug laws, [Hawaii Revised Statutes, chapter] 328 HRS;

- (E) State pharmacy law, [Hawaii Revised Statutes], chapter 461, <u>HRS</u> and [Hawaii Administrative Rules,] chapter 16-95 <u>HAR</u>; [and]
- (F) Prescription files[.] and;
- (G) Drug Facts and Comparison or other current drug information guide; and
- [(2)] (7) [The minimum technical equipment and supplies that a pharmacy shall possess are as follows:] An attestation that, at a minimum, the pharmacy possesses the following technical equipment and supplies;
 - (A) Class A prescription balance or a balance of greater sensitivity and appropriate weights;
 - (B) Mortar and pestle (glass or porcelain);
 - (C) Refrigerator;
 - (D) Bottles and vials of assorted sizes;
 - (E) Graduates or other similar measuring device; and
 - (F) Prescription labels.
- [(d)] (c) No permit shall be issued unless all deficiencies have been corrected and approved by the board.
- [(e)] (d) The board may delegate to its executive [secretary] officer the authority to issue a permit upon receipt of [the inspection report from RICO verifying that all requirements have been met.] a completed application and documentation evidencing clear compliance with this section. [Eff 5/16/64; am and ren §16-95-26, 6/22/81; am and comp 12/24/92; comp 12/25/04; am and comp

] (Auth: HRS §461-4.5) (Imp: HRS §\$461-4.5, 461-12, 461-14)

<u>Historical note:</u> The substance of this section is substantially based upon section 16-95-51. [Eff 5/16/64; am 6/11/77; am and ren §16-95-51, 6/22/81; R 12/24/92]

§16-95-27 Repealed. [R 12/24/92]

§16-95-28 Repealed. [R 12/24/92]

§16-95-29 Repealed. [R 12/24/92]

§16-95-30 Wholesale prescription drug distributor license requirements. (a) Application for a wholesale prescription drug distributor license shall be made under oath on a form to be provided by the board. In addition to providing information required by [§] section 16-95-21(b), the applicant shall provide the following information as it pertains to the applicant including any officer, director, manager, or other persons in charge of wholesale drug distribution, storage, or handling:

- (1) Any convictions under any federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;
- (2) Any felony conviction under federal, state, or local laws;
- (3) Each person's past experience in the manufacture or distribution of prescription and controlled drugs;
- (4) Any suspension [or], revocation , disciplinary action, or pending investigation by any federal, state, or local government of any license currently or previously held for the manufacture or distribution of any drugs, including controlled substances;
- (5) Verification of at least one year of experience in the distribution or handling of prescription drugs for any person responsible for the distribution of drugs; and
- (6) A current list of officers, directors, managers, and other persons in charge of the wholesale distribution, storage, and handling of prescription drugs, including a description of each person's duties and a summary of each person's qualifications.
- (b) A map of the facilities shall also be submitted. The map shall identify:
 - (1) The storage area for drugs;
 - (2) The storage area for quarantined drugs; and
 - (3) The placement of the lighting, ventilation, and temperature control equipment.
- (c) No license shall be issued prior to receipt of a satisfactory inspection report from the department of health. At a minimum, the <u>board</u> requests that department of health shall [insure] ensure that:
 - (1) The facilities are of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
 - (2) The storage areas are designed to provide adequate ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
 - (3) A quarantine area is available for prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or

- whose immediate or sealed outer or sealed secondary containers have been opened;
- (4) The facility is maintained in a clean and orderly fashion;
- (5) The facility is free from infestation by insects, rodents, birds, or vermin of any kind;
- (6) The facility is secure from unauthorized entry;
- (7) Access from outside the premises is kept to a minimum and well controlled;
- (8) The outside perimeter of the premises is well-lighted;
- (9) Entry into areas where prescription drugs are held is limited to authorized personnel;
- (10) The facilities are equipped with an alarm system to detect entry after hours;
- (11) The facilities are equipped with a security system that will provide suitable protection against theft and diversion;
- (12) All prescription drugs are stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of the drugs, or in accordance with the standards regarding conditions and temperatures for the storage of prescription drugs adopted by the state department of health.
 - (A) If no storage requirements are established for a prescription drug, the drug may be held at controlled room temperature, as defined in [an official compendium,] the current United States Pharmacopeia National Formulary and all supplements, to help ensure that its identity, strength, quality, and purity are not adversely affected;
 - (B) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be used to document the proper storage of prescription drugs;
- (13) Upon receipt, each outside shipping container of prescription drugs is examined visually to confirm the identity of the drugs and to prevent the acceptance of contaminated prescription drugs that are unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents;
- (14) Each outgoing shipment of prescription drugs is inspected carefully to confirm the identity of the drugs and to ensure that no prescription drugs are delivered that have been damaged in storage or held under improper conditions;

- (15) Returned, damaged, outdated, deteriorated, mishandled, or adulterated prescription drugs are physically separated from other prescription drugs and stored, in such a way that no cross-contamination or confusion is possible, until they are destroyed or returned to the supplier;
- (16) Any prescription drugs whose immediate or sealed outer or sealed secondary containers are found upon arrival to have been opened or used are identified as such, and are physically separated from other prescription drugs and stored, in such a way that no cross-contamination or confusion is possible, until they are destroyed or returned to the supplier; and
- (17) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug is either destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling as a result of storage or shipping.
- (d) Written policies and procedures for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories shall be submitted. Written policies and procedures shall include:
 - (1) A procedure whereby the oldest approved stock of a prescription drug is distributed first. The procedure may permit deviation from this requirement if the deviation is temporary and appropriate;
 - (2) A procedure for handling recalls and withdrawals of prescription drugs. The procedures shall be adequate to deal with recalls and withdrawals caused by:
 - (A) Any action initiated at the request of the department of health, the Food and Drug Administration, or any other federal, state, or local law enforcement or other government agency;
 - (B) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

- (C) Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design;
- (3) A procedure to ensure that the distributor prepares for, protects against, and handles properly any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or in other emergencies; and
- (4) A procedure to ensure that all outdated prescription drugs are segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall require written documentation of the disposition of outdated prescription drugs. The documentation shall be maintained for five years after disposition of the outdated drugs. [Eff and comp 12/24/92; comp 12/25/04; am and comp] (Auth: HRS §461-4.5) (Imp: §461-4.5)
- §16-95-31 <u>Miscellaneous permit.</u> An application for a miscellaneous permit shall be filed at least fifteen days before a board meeting and [must] <u>shall</u> be accompanied by the application fee, which shall not be refunded, and required fees. [Eff and comp 12/24/92; comp 12/25/04; am and comp] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 461-16)
- §16-95-32 <u>Criminal conviction</u>. When an applicant or the applicant's personnel has been convicted of a crime related to the pharmacy profession and it is determined that the conviction may be considered under section 831-3.1, HRS, the board may request the following documents from the applicant:
 - (1) Copies of any court records, <u>judgments</u>, orders, or other documents that state the facts and statutes upon which the applicant was convicted, the [verdict] <u>judgment</u> of the court with regard to that conviction, the sentence imposed, and [the actual terms of the sentence,] the record of compliance with the sentence imposed; and
 - (2) Affidavits from any parole officer, employer, or other persons who can attest to a firm belief that the applicant has been sufficiently rehabilitated to warrant the public trust. [Eff and comp 12/24/92; comp 12/25/04; am and comp] (Auth: HRS §461-4.5) (Imp: HRS §\$461-4.5, 461-21)

- §16-95-32.2 <u>Denial or rejection of application.</u> (a) An application for issuance of a license or permit shall be denied when an application is insufficient or incomplete; is not accompanied with the required fees; or when an applicant has failed to provide satisfactory proof that the applicant meets the requirements for the license or permit. In addition, the board may deny issuance of a license or permit[:] in accordance with sections 436B-19 and 461-21, HRS, and section 16-95-110.
 - [(1) When the applicant or the applicant's personnel is known to have committed any of the acts for which a license or permit may be suspended or revoked under subchapter 13; or
 - (2) If the applicant has had any disciplinary action taken by any jurisdiction, including any federal or state regulatory body.]
- (b) An application shall be automatically rejected and the applicant shall be denied a license or permit when the applicant, after having been notified to do so:
 - (1) Fails to pay the appropriate fees within sixty days from notification; or
 - (2) [Fails to submit, after notification, any of the information or documentation requested to comply with any of the requirements for licensure or certification within sixty days of notification.]

 After being requested by the board, fails to provide any information or documentation concerning the requirements for licensure or permit within sixty days of the request.
- (c) Any application which has been denied or rejected shall remain in the possession of the board and shall not be returned.
- (d) An applicant, whose application has been denied or rejected, may file for an administrative hearing pursuant to chapter 91, HRS. [Eff and comp 12/24/92; comp 12/25/04; am and comp] (Auth: HRS §461-4.5) (Imp: HRS §\$461-4.5, 461-5, 461-14, 461-15, 461-21)

EDUCATION AND EXPERIENCE DOCUMENTATION

- §16-95-33 <u>Education documentation for a pharmacist license.</u> (a) The board will accept the following as verification of education requirements for a pharmacist:
 - (1) A [photostat or certified copy of a diploma or a] certified copy of an official transcript showing the date of graduation from a college

- of pharmacy which has received candidate status with or has been accredited by the [American Council on Pharmaceutical Education (ACPE).] <u>ACPE</u>.
- (2) In lieu of the above, at the time of application, the board will accept a certified letter from the college registrar or dean verifying that the applicant is on track to graduate. However, prior to [being allowed to sit for any examination, the applicant shall provide a copy of the diploma or a certified letter from the college registrar that all credits have been completed and that the applicant has graduated] the issuance of the license, the applicant shall have complied with chapter 461, HRS, and shall have provided a certified copy of an official transcript from a college of pharmacy, which has received candidate status with or has been accredited by the ACPE and has been conferred a degree.
- (b) The board will accept the following as verification of education requirements from a foreign graduate:
 - (1) A [photostat or] certified copy of the foreign diploma or a certified copy or official transcript showing the date of graduation from the foreign college of pharmacy; and
 - (2) [Photostat] An original or certified [copies] copy of the certificates evidencing the passage of the [TOEFL, TSE, and the] FPGEE [examinations.] examination. [Eff 5/16/64; am 6/11/77; am and ren §16-95-33, 6/22/81; am and comp 12/24/92; comp 12/25/04; am and comp] (Auth: HRS §461-4.5) (Imp: HRS §461-5)
- §16-95-33.2 Education documentation for a [pharmacist assistant] pharmacy intern permit. The board will accept the following as verification of education requirements for a [pharmacist assistant] pharmacy intern permit:
 - (1) A [photostat or] certified copy of a diploma or a certified copy of an official transcript showing the date of graduation from a college of pharmacy which has received candidate status with or has been accredited by the ACPE; or
 - (2) A verification letter from the college dean or registrar that the applicant has completed the first year of pharmacy school at a school or college which has received candidate status with or has been accredited by the ACPE. [Eff and comp 12/24/92; comp 12/25/04; am and comp] (Auth: HRS §461-4.5) (Imp: HRS §8461-4.5, 461-5, 461-9)

<u>Historical note:</u> The substance of this section is based substantially upon sections 16-95-44 and 16-95-45. [Eff 5/16/64; am 8/7/70; am 6/11/77; am and ren §§16-95-44, 16-95-45, 6/22/81; R 12/24/92]

§16-95-34 Experience verification for a pharmacist by examination. (a) [The board will accept a notarized statement to verify] An applicant shall have at least [two thousand] fifteen hundred hours of practical experience under the supervision of a registered pharmacist. Practical experience shall have been acquired subsequent to graduation or completion of the first year's attendance at a school or college of pharmacy which has received candidate status with or has been accredited by the ACPE and may include:

- (1) Post graduate experience;
- (2) Supervised practice during vacations;
- (3) Experience gained concurrent with attendance at a pharmacy school; and
- (4) Experience gained during pharmacy school coordinated externships and clinical clerkship programs.
 - (A) For purposes of this section, externship means a pharmacy school coordinated practical experience program which was:
 - (i) Conducted outside the classroom in licensed pharmacies;
 - (ii) Developed to provide a broad experience in all distributive and patient oriented practice tasks;
 - (iii) Supervised by a licensed preceptor or licensed pharmacist with a one to one teaching and supervisory relationship between the preceptor or pharmacist and the extern; and
 - (iv) A component of the pharmacy school's curriculum for which academic credit is given.
 - (B) For purposes of this section, clinical clerkship means a pharmacy school coordinated practical experience program which:
 - (i) Was conducted in patient care settings where the student is provided with actual experience in patient care;
 - (ii) Placed emphasis on all phases of drug therapy relative to the disease states of individual patients;
 - (iii) Provided clinical service on either an outpatient or an inpatient basis as a primary student activity;

- (iv) May minimize general drug distributive functions; and
- (v) Is a component of the pharmacy school's curriculum for which academic credit is given.
- (b) The board will accept a [notarized] written statement of practical experience, signed by [a licensed pharmacist] an official of the licensing authority of another state, the pharmacy school, the employing pharmacy, or the supervising pharmacist who is licensed in any state or territory of the United States, attesting that the applicant worked under the [direct] immediate supervision of the pharmacist in a pharmacy in the United States or territory of the United States, selling drugs, billing prescriptions, preparing pharmaceutical preparations, and keeping records and making reports required under state and federal statutes. The statement shall also show the beginning and ending dates of the applicant's practical experience and the total number of hours worked.
- (c) The board will not accept any pro gratis practical experience hours granted upon graduation for which an applicant has not actually worked. [Eff 5/16/64; am 6/11/77; am and ren §16-95-34, 6/22/81; am and comp 12/24/92; comp 12/25/04; am and comp] (Auth: HRS §461-4.5) (Imp: HRS §461-4.5, 461-5)

<u>Historical note:</u> The substance of this section is based substantially upon sections 16-95-44, 16-95-45 and 16-95-47. [Eff 5/16/64; am 8/7/70; am 6/11/77; am and ren §§16-95-44, 16-95-45, 16-95-47, 6/22/81; R 12/24/92]

§16-95-35 Repealed. [R 12/24/92]

- §16-95-36 Experience verification for a pharmacist license by reciprocity or temporary pharmacist license. The [board will accept the following to verify two thousand] applicant for a pharmacist license by reciprocity shall provide proof or current licensure and at least fifteen hundred hours of practical experience as a registered pharmacist within five years preceding the date of application[:] in the form of:
 - (1) A statement signed by an official of the licensing authority from another state or territory of the United States, attesting that the license is current, is valid, unencumbered, and in good standing and a statement signed by the applicant's employer or employers attesting that the applicant has practiced pharmacy as a licensed

- pharmacist for [two thousand] <u>fifteen hundred</u> hours or more within the five years preceding the date of application; or
- (2) If the applicant is [not an employee, a notarized] self employed, a statement by the applicant attesting that the applicant owned and operated an independent pharmacy and that the applicant has practiced pharmacy as a licensed pharmacist for [two thousand] fifteen hundred hours or more within the five years preceding the date of application. [Eff and comp 12/24/92; comp 12/25/04; am and comp] (Auth: HRS §461-4.5) (Imp: HRS §8461-4.5, 461-5, 461-8.5)

SUBCHAPTER 4 REPEALED

§16-95-39 Repealed. [R 12/24/92]

§16-95-40 Repealed. [R 12/24/92]

SUBCHAPTER 5 REPEALED

§16-95-44 Repealed. [R 12/24/92]

§16-95-45 Repealed. [R 12/24/92]

§16-95-46 Repealed. [R 12/24/92]

§16-95-47 Repealed. [R 12/24/92]

§16-95-48 Repealed. [R 12/24/92]

§16-95-49 Repealed. [R 12/24/92]

§16-95-50 Repealed. [R 12/24/92]

SUBCHAPTER 6 REPEALED

§16-95-51 Repealed. [R 12/24/92]

§16-95-52 Repealed. [R 12/24/92]

§16-95-53 Repealed. [R 12/24/92]

§16-95-54. Repealed. [R 12/24/92]

SUBCHAPTER 7 REPEALED

§16-95-55 Repealed. [R 12/24/92]

§16-95-56 Repealed. [R 12/24/92]

§16-96-57 Repealed. [R 12/24/92]

§16-95-58 Repealed. [R 12/24/92]

§16-95-59 Repealed. [R 12/24/92]

§16-95-60 Repealed. [R 12/24/92]

§16-95-61 Repealed. [R 12/24/92]

§16-95-62 Repealed. [R 12/24/92]

§16-95-63 Repealed. [R 12/24/92]

§16-95-64 Repealed. [R12/24/92]

SUBCHAPTER 8 REPEALED

§16-95-65 Repealed. [R 12/24/92]

SUBCHAPTER 9

RENEWAL

§16-95-71 <u>Date for filing.</u> All licensees and permit holders shall complete and submit a renewal application together with the required fees on or before December 31 of the odd-numbered year. A completed renewal application with the required fees sent by the United States mail shall be considered timely filed if the envelope bears a postmark no later than December 31 of the odd-numbered year[.] or if filed on-line with the department by that date. [Eff and comp 12/24/92; comp 12/25/04; am and comp] (Auth: HRS §461-4.5) (Imp: HRS §\$461-8, 461-16)

Historical note: The substance of this section is based in part upon section 16-95-15. [Eff 5/16/64; am and ren §16-95-15, 6/22/81; R 12/24/92]

§16-95-72 <u>Automatic forfeiture for failing to renew.</u> The failure to timely renew the license or permit or to pay the applicable fees or paying fees with a check which is dishonored upon first deposit shall cause the license or permit to be automatically forfeited. [Eff and comp 12/24/92; comp 12/25/04; comp] (Auth: HRS §461-4.5) (Imp: HRS §\$461-4.5, 461-8, 461-16, Act 196, SLH 1992)

- §16-95-73 <u>Restoration of forfeited license or permit.</u> (a) A <u>forfeited</u> pharmacist license [which has been forfeited] may be restored within three years of the forfeiture provided the applicant:
 - (1) [Submits a notarized statement from a licensed pharmacist attesting that the applicant has been employed for a minimum of two thousand hours as a pharmacist within the previous five years; or] Within the first year of the forfeiture:
 - (A) Applies for restoration on a from provided by the board;
 - (B) Pays the penalty, current biennial and renewal fees; and
 - (C) Complies with the continuing education requirements under section 461-8 HRS.
 - (2) [If the applicant is licensed out-of-state, a copy of the out-of-state license and a statement signed by the out-of-state licensing official that the out-of-state license is current and in good standing and that the applicant has been employed for a minimum of two thousand hours within the preceding five years;] Within the second and third year of the forfeiture:
 - (A) Applies for restoration on a form provided by the board;
 - (B) Submits an official statement signed by the applicant's employer or employers or if the applicant was self-employed, a statement signed by the applicant attesting that the applicant has been employed for a minimum of fifteen hundred hours as a licensed pharmacist within the five years preceding the date of application;
 - (C) If applicable, provides a statement signed by a licensing official of each other state or territory of the United States in which a license is held or once held, indicating that the license is current, valid, unencumbered, and in good standing or, if the license is not current, valid unencumbered, and if any disciplinary action had been taken against the licenseE. The applicant shall be responsible for obtaining any additional information

- required by the board to review the reasons the license is not current, valid, unencumbered, or in good standing;
- [(3)] (D) Takes and passes the Hawaii [state jurisprudence examination] MPJE; and
- [(4)] (E) Pays the penalty, current biennial, and renewal fees[.] and;
 - (F) Complies with the continuing education requirements under section 461-8
- (b) A <u>forfeited</u> pharmacy or miscellaneous permit, or a wholesale distributor license [which has been forfeited] may be restored within three years of the forfeiture, provided the applicant:
 - (1) [Pays all penalty fees, current biennial, and renewal fees; and] Applies for restoration on a form provided by the board;
 - (2) [In the case of a pharmacy, passes a pharmacy inspection conducted by the regulated industries complaints office of the department; or] Pays all penalty fees, current biennial, and renewal fees;
 - (3) [In the case of a wholesale distributor, passes a facility inspection conducted by the department of health.] Submits a signed statement to report changes, if any to the information on file with the board; and
 - (4) In the case of a wholesale distributor, passes a facility inspection conducted by the department of health.
- (c) The board may deny restoration of a forfeited license or permit [against which disciplinary action has been taken since the date of forfeiture of the license or permit, or if the applicant or applicant's personnel has been convicted of any crime directly related to the practice of pharmacy, drugs, drug samples, wholesale or retail drug distribution, or distribution of controlled substances unless the conviction has been expunged or annulled or is otherwise precluded from consideration by chapter 831-3.1, HRS.] if during the time the license or permit was forfeited, the license or permit holder engaged in any activities identified in section 436B-19 or 461-21, HRS, or both.
- (d) A person whose license or permit has been forfeited and who fails to restore the license or permit as provided in this section, shall apply as a new applicant. [Eff and comp 12/24/92; comp 12/25/04; am and comp] (Auth: HRS §461-4.5) (Imp: HRS §461-4.5, 461-8, 461-16)

<u>Historical note:</u> The substance of this section is based substantially upon sections 16-95-16 and 16-95-17. [Eff 5/16/64; am 3/16/80; am and ren §\$16-95-16, 16-95-17, 6/22/81; R 12/24/92]

- §16-95-74 <u>Board may refuse to renew [or restore.] a license or permit.</u> (a) The board may refuse to renew or restore a license or permit for failure or refusal of the licensee or permit holder to:
 - (1) Properly complete or timely submit the renewal application form and submit all fees and required documentation;
 - (2) Meet and maintain the conditions and requirements necessary to qualify for the issuance of the license or permit; and
 - (3) Comply with chapter 461, HRS, and this chapter.
- (b) An applicant, whose application has not been renewed or restored for the above reasons, may file for an administrative hearing [as provided for in subchapter 13] <u>pursuant to chapter 91, HRS</u>. [Eff and comp 12/24/92; comp 12/25/04; am and comp] (Auth: HRS §461-4.5) (Imp: HRS §461-4.5)

SCOPE OF PRACTICE

- §16-95-79 <u>Supervision by a registered pharmacist.</u> (a) A <u>registered</u> pharmacist shall [directly] <u>immediately</u> supervise all activities and operations of a pharmacy, and <u>immediately supervise</u> the functions and activities of [pharmacist assistants] <u>pharmacy interns</u> and pharmacy technicians to [insure] <u>ensure</u> that all functions and activities are performed in accordance with [procedures and the scope of a pharmacist assistant or a pharmacy technician and further shall initial all prescriptions filled by pharmacist assistants and pharmacy technicians] <u>laws</u> and rules governing the practice of pharmacy.
- (b) A pharmacist either employed within an institutional facility or providing services to an institutional facility shall be responsible for ensuring that the institutional facility establishes, maintains, and operates in accordance with written policies and procedures as outlined in section 16-95-80. [Eff and comp 12/24/92; comp 12/25/04; am and comp] (Auth: HRS §461-4.5) (Imp: HRS §\$461-4.5, 461-9, 461-10, 461-11, 461-12, 461-13)

<u>Historical note:</u> The substance of this section is based in part on section 16-95-46. [Eff 5/16/64; am and ren §16-95-46, 6/22/81; R 12/24/92]

§16-95-80 <u>Physical presence of a registered pharmacist.</u> (a) <u>A registered pharmacist [must] shall</u> be physically present during the hours of operation of a prescription area.

- (b) At any time a registered pharmacist is not in the prescription area, (except in cases of emergencies), the entire stock of prescription drugs shall be secured from access to unauthorized persons and the means of access shall only be in the [possession] control of the pharmacist.
- (c) A pharmacist in an institutional pharmacy shall ensure that written policies and procedures have been established by the institutional facility for [provision of] providing drugs to the medical staff and other authorized personnel of the institutional facility by use of night cabinets, and access to the institutional pharmacy and emergency kits when the pharmacist is not in the area. A [night cabinet] "night cabinet" is a cabinet, room, or any other enclosure not located within the prescription area. The written policies and procedures shall provide that a pharmacist shall be "on call" during those periods when night cabinets are utilized and shall provide policies and procedures regarding the following:
 - (1) Security of the night cabinet to ensure that the night cabinet is sufficiently secured to deny access to unauthorized persons by force or otherwise;
 - (2) The development <u>and maintenance</u> of an inventory listing of all drugs included in the cabinet and the requirement that the pharmacist ensures, at a minimum, that:
 - (A) Drugs available therein are properly labeled;
 - (B) Only prepackaged drugs are available therein in amounts sufficient for immediate therapeutic requirements; and
 - (C) [A prescription is attached to the inventory list for any drug that was withdrawn from the cabinet;] An appropriate practitioner's prescription regarding the dispensing of drugs exists.
 - [(D) All drugs therein are inventoried no less than once per calendar quarter; and
 - (E) A complete audit of all activity concerning such cabinet is conducted no less than once per month.]
 - (3) Access to the pharmacy. In the event a drug is not available from floor supplies or night cabinets and the drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, the drug may be obtained from the institutional pharmacy in accordance with this subsection. Authorized personnel may remove drugs therefrom provided:

- (A) The authorized personnel are designated, in writing, by the institutional facility;
- (B) The authorized personnel have been instructed by the pharmacist of the proper methods of access, and the records and procedures regarding removal of the drugs; and
- (C) The authorized personnel are required to complete a form which shall include the patient's name and room number, the name of drug, drug strength, dosage, quantity of drug removed, date, time, and the signature of the authorized personnel.
- [Use of drugs that have a "stop date." For purposes of this section, (4)"stop date" in an institutional setting is the length of time to administer a medication as indicated on a drug order. In the absence of such a notation, if an order is necessary or advisable to stop the particular drug, a committee of the institutional facility will have determined by policy, the length of time for administration of the drug.] The prompt detection, removal, disposal, handling, and replacement, if possible, of a drug which has been recalled by the U.S. Food and Drug Administration or the manufacturer to ensure that recalled drugs are removed from the pharmacy's inventory, emergency kit, night cabinet, remote dispensing machine, or from the patient if deemed necessary according to the federal and manufacturer's guidelines. [Eff and comp 12/24/92; comp 12/25/04; am and comp (Auth: HRS §461-4.5) (Imp: HRS §§461-1, 461-4.5, 461-9, 461-10, 461-11, 461-12)

<u>Historical note:</u> The substance of this section is based in part on section 16-95-4. [Eff 5/16/64; am and ren §16-95-4, 6/22/81; R 12/24/92]

- §16-95-81 Emergency kits. (a) A pharmacist may provide emergency kits to an institutional facility which does not have an institutional pharmacy to meet the immediate therapeutic needs of patients.
- (b) The pharmacist and the medical staff of the institutional facility shall jointly determine the drugs, and quantity, to be included in the emergency kit.
- (c) The exterior of emergency kits shall be labeled by the pharmacist to clearly [and unmistakenly] indicate that the kit is an emergency drug kit [and that the kit is for use in emergencies only]. In addition, [the label shall also

contain] there shall be a listing of the drugs contained [therein,] in the emergency kit, including name, strength, quantity, and expiration date of the [contents, and] drugs, which shall be maintained and kept in an accessible location near to the emergency kit, along with the name, address, and telephone number of the supplying [pharmacist.] pharmacy.

- (d) All drugs contained within the emergency kit shall be labeled to identify, at a minimum, the brand or generic name, strength, route[,] of administration, if other than oral, quantity, source, manufacturer, if generic, lot number, expiration date, and other information as may be required by the medical staff of the institutional facility to prevent any misunderstanding or risk of harm to the patients of the facility.
- (e) On or before the earliest expiration date of any drug contained in the emergency kit, the pharmacist shall replace any expired drugs, relabel, and reseal the kit.
- (f) The pharmacist shall ensure that the institutional facility has established written policies and procedures which shall provide, but not be limited to, policies and procedures covering:
 - (1) Storage of emergency kits in secured areas which shall be in an environment for preservation of the drugs;
 - (2) Procedures to ensure that drugs are removed only pursuant to a valid prescription or practitioner's order and recordation of any removal; and
 - (3) Procedures to notify the pharmacist within twenty-four hours of any removal of any drug from the emergency kit. [Eff and comp 12/24/92; comp 12/25/04; am and comp]

 (Auth: HRS §461-4.5) (Imp: HRS §8461-1, 461-9, 461-10, 461-11, 461-12)

§16-95-82 <u>Valid prescriptions</u>. (a) A pharmacist may fill and dispense prescriptions provided the prescription is valid. A valid prescription shall be legibly written and contain, at the minimum, the following information:

- (1) The date of issuance;
- (2) The original signature of the [prescriber;] <u>practitioner</u>;
- (3) The [prescriber's] <u>practitioner's</u> name and business address;
- (4) The name, strength, quantity, and [directions;] <u>specific instructions</u> for the drug to be dispensed;
- (5) The name and address of the person for whom the prescription was [filled] <u>written</u> or the name <u>of the animal</u> and address of the owner

- of the animal for which the drug is prescribed, [(]unless the pharmacy filling the prescription has such address on file[)];
- (6) The room number and route of administration if the patient is in an institutional facility; and
- (7) If refillable, the number of allowable refills.
- (b) Except where a written prescription is required by law <u>a</u> <u>practitioner or the practitioner's agent may use</u> a phone order [is acceptable from prescribers or their authorized agent] provided:
 - (1) Only a pharmacist <u>or a pharmacy intern</u> shall receive the oral prescription;
 - (2) The oral prescription [is] shall be [promptly] immediately reduced to writing, including the practitioner's oral code designation, by the pharmacist or pharmacy intern and shall [and] be kept on file for five years; and
 - (3) The oral prescription contains all of the information required under subsection (a).
- (c) A faxed prescription for a noncontrolled substance <u>sent by a practitioner or the practitioner's agent</u> is acceptable [from prescribers provided the facsimile is sent by the prescriber or the prescriber's authorized agent, and] <u>provided it contains all of the information required under subsection (a) and is kept on file for five years.</u>
 - [(d) No prescription which is coded shall be filled or dispensed.
- (e)] (d) Any pharmacist shall comply with any applicable state or federal laws or rules governing the validity of prescriptions. [Eff and comp 12/24/92; comp 12/25/04; am and comp] (Auth: HRS §461-4.5) (Imp: HRS §8461-11, 461-13)

<u>Historical note:</u> The substance of this section is based in part upon sections 16-95-9 and 16-95-10. [Eff 5/16/64; am and ren §§16-95-9, 16-95-10, 6/22/81; R 12/24/92]

- §16-95-83 <u>Substitution</u>; <u>drug product selection</u>. (a) It shall be unlawful to dispense a different drug in place of the drug prescribed without the express consent of the person prescribing.
- (b) Drug product selection shall comply with [Part] <u>part</u> VI of chapter 328, HRS. [Eff and comp 12/24/92; comp 12/25/04;am and comp] (Auth: HRS §461-4.5) (Imp: HRS §\$328-92, 328-94, 328-97, 328-98, 461-11, 461-13, 328)

Historical note: The substance of this section is based in part upon section 16-95-83 is based substantially upon \$16-95-11. [Eff 5/16/64; am and ren \$16-95-11, 6/22/81; R 12/24/92]

§16-95-84 <u>Transfer of prescriptions.</u> (a) Transfers of prescription information for the purpose of refill dispensing is permissible between pharmacies provided the pharmacist transferring the prescription provides all information necessary for a valid prescription, and[:

- (1) Writes the words "void" and "invalid" on the face of the prescription; and
- (2) Records] records on the [reverse side of the] prescription, the name and location of the pharmacy receiving the prescription, the name of the pharmacist receiving the prescription information, the date of transfer, [and] the name of the pharmacist transferring the prescription[.] or note the pharmacist's name on the electronic files, and record that the prescription is inactivated or made void for future refills at the location from which it is being transferred.
- (b) The pharmacist receiving the transferred prescription information shalls:
 - (1) Write the word "Transfer" on the face of the valid transferred prescription; and
 - (2) The indicate the name of the pharmacist transferring the prescription as well as the transferring pharmacist's or [pharmacy's] pharmacy name, the transferring pharmacy's name, location, and original prescription number[.], the original date the prescription was written, the number of refills or quantity remaining on the prescription, and the last date the prescription was filled.
- (c) All records of transferred prescriptions shall be maintained for a period of five years from the date of filling or refilling.

 [Eff and comp 12/24/92; comp 12/25/04; am and comp]

 (Auth: HRS §461-4.5) (Imp: HRS §8461-10, 461-11, 461-13)

§16-95-85 Scope of practice of a pharmacy intern. A pharmacy intern may perform all functions under the definition of "practice of pharmacy" as stated in section 461-1 HRS, except where prohibited by any state or federal law or rule and excluding the final drug verification before it is dispensed. The pharmacy intern shall at all times be under the immediate supervision of a licensed or registered pharmacist. [eff and comp]

- §16-95-86 Scope of practice of a pharmacy technician. A pharmacy technician may perform the following tasks, not requiring professional judgment, under the immediate supervision of a pharmacist:
 - (1) [Typing of] <u>Process</u> prescription labels, drug packaging, stocking, delivery, record keeping, pricing, documentation of third party reimbursements, and preparing, <u>labeling</u>, compounding, storing, and providing medication;
 - (2) [Mixing drugs with parenteral fluids] <u>Medication preparation is</u> permissible provided that the pharmacy technician:
 - (A) Has a working knowledge of the pharmaceutical medical terms, abbreviations, and symbols commonly used in the prescribing, dispensing, and charting of medications;
 - (B) Is able to perform the arithmetic calculations required for the usual dosage determination and solution preparation;
 - (C) Has a thorough knowledge and understanding of the pharmacy technician's duties and responsibilities, including standards of ethics and applicable laws and regulations governing the practice of pharmacy;
 - (D) Has a working knowledge of drug dosages, route of administration, and dosage forms[;] and therapeutics:
 - (E) Has a working knowledge of the procedures and operations relating to the manufacturing, packaging, and labeling of drug products; and
 - (F) Has [a] an appropriate working knowledge of the procedures and operations relating to aseptic compounding and parenteral admixture operations. [Eff and comp 12/24/92; comp 12/25/04; am and comp] (Auth: HRS §461-4.5) (Imp: HRS §§461-9, 461-10, 461-11)

§16-95-87 Return or exchange of drugs prohibited. No prescription drug shall be accepted for return or exchange after [such] the drug has been taken from the premises where dispensed or sold by prescription. [Eff and comp 12/24/92; comp 12/25/04; am and comp] (Auth: HRS §461-4.5) (Imp: HRS §461-11)

<u>Historical note:</u> Section 16-95-87 is substantially identical to section 16-95-12. [Eff 5/15/64; am and ren §16-95-12, 6/22/81; R 12/24/92]

RECORD KEEPING REQUIREMENTS

§16-95-93 <u>Records of dispensing.</u> (a) Records of dispensing for original and refill prescriptions are to be made and kept by pharmacies for five years and, in addition to the requirements of section 16-95-82, shall include[,] but not be limited to[,] the following:

- (1) Quantity prescribed and quantity dispensed;
- (2) Date of dispensing;
- (3) Serial number or, if an institution, equivalent control system;
- (4) Identification of the pharmacist responsible for dispensing; and
- (5) Record of refills to date.
- (b) An institutional pharmacy will have fulfilled the requirements of this section if the information required by paragraphs (1) to (4) of subsection (a) is kept on accurate patient profiles or medication administration records showing all drugs administered to the patient for five years; and the institutional facility keeps the original patient charts evidencing the prescription orders and medication administration records in the institutional facility's files for at least five years. [Eff and comp 12/24/92; comp 12/25/04; am and comp] (Auth: HRS §461-4.5) (Imp: HRS §\$461-4.5, 461-10, 461-11, 461-13)

§16-95-94 <u>Automated data processing systems.</u> As an alternative to procedures set forth in section16-95-93, an [automated data processing] <u>ADP</u> system may be employed for the record keeping system provided the following conditions have been met:

- (1) The [automated data processing (ADP)] <u>ADP</u> system shall have the capability of producing hard copy documents of all drug orders of original and refilled prescription information. The hard copy produced must be of a print size that is readable without the aid of any special device;
- (2) Information to be kept on the ADP system shall include, but not be limited to[,]the information required in section 16-95-82, valid prescriptions, and section 16-95-93, records of dispensing;
- (3) The pharmacist responsible for entries into the ADP system shall ensure that the information entered into the computer is accurate and complete;

- (4) The documentation used to satisfy the above requirements shall be provided to the pharmacy within seventy-two hours of the date of dispensing;
- (5) An auxiliary record keeping system shall be established for the documentation of refills in the event the ADP system is inoperative for any reason. The auxiliary system shall [insure] ensure that all refills are authorized by the original prescription and that the maximum number of refills is not exceeded. When the ADP system is restored to operation, the information regarding drug orders and prescriptions filled and refilled during the inoperative period shall be entered in the ADP system within ninety-six hours;
- (6) Any pharmacy using an ADP system shall comply with all applicable state and federal laws, rules, and regulations; and

§16-95-95 <u>Security of records.</u> To maintain the confidentiality of patient's prescriptions or drug orders, there shall exist adequate safeguards for security of the records whether kept manually or in an ADP system. [Eff and comp 12/24/92; comp 12/25/04; comp] (Auth: HRS §461-4.5) (Imp: HRS §461-9, 461-10, 461-11, 461-12, 461-13)

§16-95-96 Record keeping for wholesale prescription drug distributors.

(a) Wholesale distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These inventories and records shall include the following information:

(1) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

- (2) The identity and quantity of the drugs received and distributed or disposed of; and
- (3) The dates of receipt and distribution or other disposition of the drugs.
- (b) The wholesale distributor shall also maintain records to reflect:
- (1) Storage. All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with the requirements, if any, in the labeling of the drugs, or in accordance with the standards regarding conditions and temperatures for the storage of prescription drugs.
 - (A) If no storage requirements are established for a prescription drug, the drug may be held at controlled room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.
 - (B) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be used to document the proper storage of prescription drugs.
- (2) Examination of materials.
 - (A) Documentation shall be maintained for at least five years demonstrating that each outside shipping container of prescription drugs was examined visually to confirm the identity of the drugs and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution shall be maintained. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
 - (B) Documentation shall be maintained for at least five years demonstrating that each outgoing shipment of prescription drugs was inspected carefully to confirm the identity of the drugs and to ensure that no prescription drugs were delivered that have been damaged in storage or held under improper conditions [shall be maintained].
- (3) Returned, damaged, outdated, deteriorated, misbranded, and adulterated prescription drugs.
 - (A) Prescription drugs that are damaged, outdated, deteriorated, misbranded, or adulterated shall be physically separate from other prescription drugs and stored, in such a way that no

- cross-contamination or confusion are possible, until they are destroyed or returned to the supplier.
- (B) Any prescription drugs whose immediate or sealed outer or sealed secondary containers are found upon arrival to have been opened or used shall be identified as such, and shall be physically separated from other prescription drugs and stored, in such a way that no cross-contamination or confusion are possible, until they are destroyed or returned to the supplier.
- (C) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be either destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, quality, or purity, the wholesale distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling as a result of storage or shipping.
- (c) Inventories and records shall be made available for inspection and photocopying by the department or any authorized federal, state, or local law enforcement officials for a period of five years following disposition of the drugs.
- (d) Records described in this section that are kept at the inspection site or that can be retrieved immediately by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by the department or any authorized official of a federal, state, or local law enforcement agency. [Eff and comp 12/24/92; comp 12/25/04; am and comp] (Auth: HRS §461-4.5)

ADVERTISING PRACTICES

§16-95-101 Procedures to advertise prescription drugs. (a) Advertising of prescription drugs is to provide the public with information in a manner consistent with public health and safety. Prescription drug advertising is for the purpose of providing information and not to create a demand for drugs. A pharmacy, if it chooses to advertise, will advertise prescription prices, drugs, and reference to prescription prices and drugs in accordance with this section:

- (1) A pharmacy may post its prices for prescription drugs on a prescription price poster. The form of [such] the posting shall be legible.
- (2) A pharmacy may advertise prescription prices by publication or display in any media. For purposes of this section, "media" includes[,] but is not limited to[,] newspapers, magazines, calling cards, and directories, including all listings in telephone directories.
- (3) Any advertisement for prescription drugs shall be made in three commonly prescribed quantities.
- [(4) Any advertisement for prescription drugs shall contain the brand name of that drug.]
- [(5)] (4) Any advertisement for prescription drugs or prices shall be truthful, reasonable, fully informative, and understandable to the public and shall not be false or misleading.
- [(6)] (5) Any advertisement for prescription drugs shall state the time period during which the prices advertised will be effective.
- (b) The price for prescription drugs advertised shall not be below cost as defined in section 481-3, HRS, as amended.
- (c) A pharmacist or the pharmacist's agent upon request however communicated to the pharmacist shall give the current price for any drug sold at the pharmacist's pharmacy for informational purposes only and [such] the price quoted shall not be false or misleading but must be truthful, reasonable, informative, and understandable to the public. [Eff and comp 12/24/92; comp 12/25/04; am and comp] (Auth: HRS §§461-1, 461-4.5, 461-21)

<u>Historical note:</u> The substance of this section is substantially identical to sections 16-95-5, 16-95-6 and 16-95-7. [Eff 5/16/64; 9/1/74; am 2/3/78; am and ren §§16-95-5, 16-95-6, 16-95-7, 6/22/81; R 12/24/92]

- §16-95-102 <u>Procedures to advertise related pharmacy services.</u> Advertising of related pharmacy services is to provide the public with information in a manner consistent with public health and safety and shall be truthful, reasonable, fully informative, and understandable to the public and shall not be false or misleading. A pharmacy may advertise that it performs the following services:
 - (1) Personal medication record. To qualify as providing this service, a system must be maintained which enables the immediate retrieval of information concerning individual pharmacy patients which is of sufficient scope to enable a determination by the pharmacist of rational drug utilization. In accomplishing this purpose the design and use of the system must be to ascertain and record all patient information necessary to assist the pharmacist in avoiding adverse drug reactions, drug-drug interactions, and inappropriate use of drugs.
 - Professional consultation with patient and [doctor.] <u>practitioners</u>. The availability of patient consultation means that the pharmacist routinely informs the patient, either directly or indirectly, on what the patient is taking, how to take it, what to expect, what special precautions should be observed, and how the medication is to be properly stored. This service is to assure that the patient understands the proper use of the drug and that the [physician's] <u>practitioner's</u> intentions will materialize in a drug regimen of optimal effectiveness, safety, and duration. [Doctor or prescriber] <u>Practitioner</u> consultation denotes the availability and practice of pharmacists acting as drug information specialists who discuss with [prescribers] <u>practitioners</u> drug [effect,] <u>effects</u> interactions, side effects, and drugs of choice for diseased conditions.
 - (3) "Emergency prescription service" means the providing of pharmaceutical services, which includes prescription dispensing, at any time after usual pharmacy hours. This means that a pharmacist is available, can be readily contacted, and will respond with reasonable expediency at any hour, day or night, in a manner consistent with security and personal safety.

Should the pharmacy choose to advertise the performance of the foregoing services, it [must] shall conform with the definition of that service as herein set forth. [Eff and comp 12/24/92; comp 12/25/04; am and comp] (Auth: HRS §461-4.5) (Imp: HRS §\$461-1, 461-4.5, 461-21.)

Historical note: The substance of this section is based substantially on section 16-95-5. [Eff 5/16/64; am 2/3/78; am and ren §16-95-5, 6/22/81; R 12/24/92]

§16-95-103 Advertising of controlled substances prohibited. No person shall advertise or promote to the public in any manner the sale of a Scheduled II, III, IV, or V controlled substance as defined in the Federal Controlled Substances Act and the rules promulgated thereunder as well as any other controlled substances as defined in chapter 329, HRS, as amended, and the rules promulgated thereunder by the state department of health. [Eff and comp 12/24/92; comp 12/25/04; comp] (Auth: HRS §461-4.5) (Imp: HRS §461-4.5)

Historical note: The substance of this section is substantially identical to section 16-95-8. [Eff 9/1/74; am 2/3/78; am and ren §16-95-8, 6/22/81; R 12/24/92]

SUBCHAPTER 13

DISCIPLINARY SANCTIONS, APPLICATION DENIAL, HEARINGS, ADMINISTRATIVE PRACTICE AND PROCEDURE

§16-95-110 Grounds for revocation, suspension, refusal to renew or restore, denial, or conditioning of license or permit. (a) In addition to any other acts or conditions provided by law, the board may revoke, suspend, refuse to renew or restore, deny, or condition a license or permit for any one or more of the following acts or omissions:

- (1) Procuring a license or permit through misrepresentation or deceit;
- (2) Failing to meet or maintain the requirements or conditions necessary to qualify for license or permit;
- (3) Conviction of, or pleading nolo contendere to a crime that is substantially related to the qualification, functions, or duties of a pharmacist;
- (4) Committing any act or omission in the practice of pharmacy or wholesale distribution which constitutes dishonesty, fraud, or misrepresentation with the intent to substantially benefit the pharmacist or wholesale distributor or with the intent to substantially injure another person;
- (5) Aiding or abetting an unlicensed person to directly or indirectly evade chapter 461, HRS, or this chapter;

- (6) Failing to maintain records or to make accessible any records as required in subchapter 11;
- (7) Violating any provisions of the department of health or department of public safety;
- (8) [Accepting] Except as provided by law, accepting returns or exchanges of prescription drugs after [such] the drugs [had] have been [taken from the premises where it was dispensed or sold by a prescription; dispense;] dispensed;
- (9) Dispensing a different drug or brand in place of the drug or brand prescribed without the express consent of the person prescribing;
- (10) Failing to comply with the state's drug formulary or substitution laws as set forth in part VI of chapter 328, HRS;
- (11) Professional misconduct, gross carelessness, or manifest incapacity;
- (12) Violation of any state or federal <u>law, including violation of a drug,</u> controlled substance, or poison law;
- (13) False, fraudulent, or deceptive advertising;
- (14) Making a false statement on any document submitted or required to be filed by this chapter;
- (15) Habitual intemperance or addiction to the use of habit-forming drugs;
- (16) Violating the provisions of chapter 461, HRS, this chapter, or any order of the board.
- Failure to comply with the pharmaceutical compounding requirements found in Chapters 795 (nonsterile preparations) and 797 (sterile preparations) of the United States Pharmacopeia National Formulary, as amended;
- Failure to report, in writing to the licensing authority, any disciplinary decision issued against the licensee or the applicant in another jurisdiction within thirty days of the disciplinary decision.
- (b) The board may make recommendations regarding quality improvements to prevent or minimize errors. The board may also fine or impose conditions or limitations upon a license or permit. [after a] A hearing on that fine, condition, or limitation may be conducted in accordance with chapter 91, HRS. The violation of any condition or limitation on a license or permit may be cause to impose additional sanctions against the licensee or permittee. Any fine imposed by the board after a hearing in accordance with chapter 91, HRS, shall be no less than \$100 and no more than \$1,000 for each violation, and each day of violation may be deemed a separate violation. [Eff and comp 12/24/92; comp 12/25/04; am

and comp] (Auth: HRS §461-4.5) (Imp: HRS §\$461-4.5, 461-17, 461-21, 461-22,)

§16-95-111 <u>Denial</u>. In the event an application for the issuance of a license or permit or for the reinstatement thereof is denied, the board shall notify the applicant by letter of the board's action which shall include a concise statement of the reasons therefor and a statement informing the applicant of the applicant's right to a hearing if the applicant so desires. [Eff and comp 12/24/92; comp 12/25/04; comp] (Auth: HRS §461-4.5) (Imp: HRS §461-4.5, 461-8, 461-14, 461-21, 461-22)

Historical note: The substance of this section is substantially identical to section 16-95-27. [Eff 5/16/64; am and ren §16-95-27; 6/22/81; R 12/24/92]

- §16-95-112 <u>Demand for hearing</u>; proceedings upon demand for hearing. (a) Any person whose application for a license or permit or whose application for the reinstatement of a license or permit has been denied by the board shall be entitled to a hearing, provided that a demand for a hearing is filed with the board within sixty days of the date of denial of the application.
- (b) If a demand for hearing is filed within the time prescribed, the board shall order a hearing in accordance with chapter 91, HRS, relating to contested cases and unless the context otherwise requires, the rules set forth in chapter 16-201, [Hawaii Administrative Rules,] the rules of practice and procedure of the department. [Eff and comp 12/24/92; comp 12/25/04; am and comp

 [(Auth: HRS §461-4.5) (Imp: HRS §§91-9, 91-9.5, 91-10, 91-11, 91-12, 461-4.5, 461-21)

<u>Historical note:</u> The substance of this section is substantially identical to sections 16-95-28 and 16-95-29. [Eff 5/16/64; am and ren §§16-95-28, 16-95-29, 6/22/81; R 12/24/92]

§16-95-113 <u>Administrative practice and procedure.</u> The rules of practice and procedure for pharmacies and pharmacists shall be as provided in chapter 16-201, the rules of practice and procedure of the department as adopted, and as may subsequently be amended, which are incorporated by reference and made a part of this chapter. [Eff and comp 12/24/92; comp 12/25/04; comp] (Auth: HRS §461-4.5) (Imp: HRS §891-2, 461-4.5)

ORAL TESTIMONY

§16-95-118 Oral testimony. (a) The board shall accept oral testimony on any item which is on the agenda, provided that the testimony shall be subject to the following conditions:

- (1) Each person seeking to present oral testimony is requested to notify the board not later than forty-eight hours before the meeting, and at that time to state the item on which testimony is to be presented;
- (2) The board may request that any person providing oral testimony submit the remarks, or a summary of the remarks, in writing to the board;
- (3) The board may rearrange the items on the agenda for the purpose of providing for the most efficient and convenient presentation of oral testimony;
- (4) Persons presenting oral testimony at the beginning of the testimony shall identify themselves and the organization, if any, that they represent;
- (5) The board may limit oral testimony to a specified time period but in no case shall the period be less than five minutes, and the person testifying shall be informed prior to the commencement of the testimony of the time constraints to be imposed; and
- (6) The board may refuse to hear any testimony which is irrelevant, immaterial, or unduly repetitious to the agenda item on which it is presented.
- (b) Nothing in this section shall require the board to hear or receive any oral or documentary evidence from a person on any matter which is the subject of another proceeding pending subject to the hearings relief, declaratory relief, or rule relief provisions of chapter 16-201.
- (c) Nothing in this section shall prevent the board from soliciting oral remarks from persons present at the meeting or from inviting persons to make presentations to the board on any particular matter on the board's agenda. [Eff and comp 12/24/92; comp 12/25/04; am and comp] (Auth: HRS §461-4.5) (Imp: HRS §§92-3, 461-4.5)

FEES

§16-95-123 <u>Fees established.</u> The fees are as established in chapter 16-53. The fees for wholesale prescription drug distributors license shall be the same fees as established for a pharmacy in chapter 16-53. [Eff and comp 12/24/92; comp 12/25/04; comp] (Auth: HRS §461-4.5) (Imp: HRS §§461-4.5, 26-9)

§16-95-124 Form of fee. The fees, if in the form of a money order or check, shall be made payable to the department [of commerce and consumer affairs]. [Eff and comp 12/24/92; comp 12/25/04; am and comp] (Auth: HRS §461-4.5) (Imp: HRS §461-4.5)

§16-95-125 <u>Dishonored checks considered failure to meet requirements.</u>
The dishonoring of any check upon first deposit shall be considered a failure to meet requirements. [Eff and comp 12/24/92; comp 12/25/04; comp] (Auth: HRS §461-4.5) (Imp: HRS §461-4.5)

SUBCHAPTER 16

EMERGENCY CONTRACEPTION COLLABORATIVE AGREEMENT

- §16-95-130 Emergency contraception written collaborative agreement.

 (a) Each arrangement between a licensed pharmacist and a licensed physician relating to the distribution to a patient of emergency contraception drugs shall be documented in a signed collaborative agreement in accordance with the form attached hereto as Exhibit "A" entitled Emergency Contraception Drug Therapy Collaborative Agreement dated 1204, located at the end of this chapter and made a part of this chapter. The agreement shall be delivered to the [department] board by the licensed pharmacist within [seven] ten days of the execution of the agreement by the pharmacist and the physician.
- (b) Before a pharmacist may participate in the collaborative agreement, the pharmacist shall have completed an emergency contraception training course approved by the [American Council of Pharmaceutical Education (ACPE),] ACPE, curriculum-based programs from an ACPE-accredited college of

pharmacy, applicable state or local health department programs, or programs recognized by the board of pharmacy. Training shall include procedures listed in Exhibit "A", the management of the sensitive communications often encountered in emergency contraception, providing service to minors, quality assurance, referral for additional services, and documentation[, and a crisis plan if the pharmacy operations are disrupted by individuals opposing the emergency contraception].

- (c) By executing the collaborative agreement, both the physician and pharmacist agree and acknowledge that:
 - (1) They accept the responsibility for the distribution of the emergency contraception drugs and that the licensed pharmacist shall dispense only certain drugs approved for emergency contraception by the United States Food and Drug Administration. [The] Some of the currently approved drugs are listed in the attached Exhibit "B" entitled brands and doses, dated 0814 located at the end of this chapter and made a part of this chapter[. Plan B®, an oral contraceptive manufactured by Women's Capital Corporation (or generic equivalent), shall be the preferred drug therapy.] however, drugs approved for emergency contraception are not limited to this list. Other drugs listed in Exhibit "B" may be dispensed instead of Plan B® in the following circumstances:
 - (A) Plan B® is unavailable;
 - (B) Plan B® is not covered under the patient's health insurance plan and another drug listed in Exhibit "B" is covered; or
 - (C) The patient chooses another listed drug after the pharmacist advises the patient that side effects are usually less with Plan B®.

The list of approved drugs in Exhibit "B" also shall include adjunctive drugs for treatment of nausea and vomiting that may be associated with emergency contraceptives;

- (2) The licensed pharmacist shall provide the patient with drug information concerning dosage, potential adverse side effects, and follow-up contraceptive care;
- (3) The collaborative agreement shall be effective for a period of at least two years from the date of its delivery to the [department] board, unless rescinded in writing [earlier] by either the physician or the pharmacist, with written notice to the other and the [department] board, or unless the pharmacy board invalidates the agreement or changes the terms of the agreement. After the two year period, the agreement shall continue to be valid from month to

month unless rescinded, invalidated, or changed as provided herein. The licensed pharmacist or the licensed physician, who rescinds the agreement, shall notify the [department] <u>board</u> within three business days of the rescission. At the time the collaborative agreement is rescinded, the licensed pharmacist shall not have prescriptive authority to dispense emergency contraceptives until another collaborative agreement with a physician is completed and [delivered to] <u>received by</u> the [department;] board; and

- (4) Each drug therapy prescription authorized by the physician and dispensed by the pharmacist shall be documented in a patient profile.
- (d) Additionally, the collaborative agreement between the licensed pharmacist and licensed physician shall include:
 - (1) The name, address, and phone number of the licensed pharmacist and pharmacy and the signature of the licensed pharmacist;
 - (2) The name, address, and phone number of the licensed physician and the signature of the licensed physician;
 - (3) The purpose of the collaborative agreement, which is to permit emergency contraception drug therapy within one hundred and twenty hours of the patient having unprotected sexual contact and to ensure that the patient receives appropriate information from the licensed pharmacist regarding the drug therapy;
 - (4) The procedures, delineated in Exhibit "A", to be followed by the licensed pharmacist when the patient requests drug therapy, including any applicable referrals;
 - (5) Any limitation agreed upon by both the licensed pharmacist and the licensed physician including, but not limited to, approved drugs that may not be prescribed to the patient or whether the licensed pharmacist's or the licensed physician's decision shall control in the event of a disagreement on the prescription for a patient;
 - (6) A provision that the licensed pharmacist shall refer the patient to [the] <u>a</u> licensed physician;
 - (7) A statement that the label placed on the drug therapy product shall contain the names of both the pharmacist and the physician signers of this Agreement;
 - (8) An informed consent, included in Exhibit "A", to be used by the licensed pharmacist to inform the patient about the emergency contraception drug therapy. The informed consent shall be signed by both the licensed pharmacist and the patient; and

- (9) A screening checklist for emergency contraception pills, included in Exhibit "A", to be filled in by the patient and signed by both the licensed pharmacist and the patient.
- (e) Any modification to an existing collaborative agreement previously delivered to the [department] <u>board</u> shall be submitted [also] to the [department] <u>board</u> by the licensed pharmacist at least ten working days prior to the intended implementation of the changed collaborative agreement.
- (f) The board [of pharmacy] shall have the authority to reject a collaborative agreement if the board determines that the collaborative agreement is not in compliance with this section or is not in the best interests of the patient.
- (g) The form of the collaborative agreement, the informed consent form, and the screening checklist for emergency contraception drugs attached as Exhibit "A" hereto, shall be made available by the board to licensed pharmacists and licensed physicians." [Eff and comp 12/25/04; am and comp] (Auth: HRS §461-4.5) (Imp: HRS §461-1)

- 2. Material, except source notes, to be repealed is bracketed. New material is underscored.
- 3. Additions to update source notes to reflect these amendments and compilation are not underscored.
- 4. These amendments to and compilation of chapter 16-95, Hawaii Administrative Rules, shall take effect ten days after filing with the Office of the Lieutenant Governor.

I certify that the foregoing are copies of the rules drafted in the Ramseyer format pursuant to the requirements of section 91-4.1, Hawaii Revised Statutes, which were adopted on and filed with the Office of the Lieutenant Governor.

lein Olamin

KERRI OKAMURA Chairperson, Board of Pharmacy

APPROVED AS TO FORM:

Deputy Attorney General

EXHIBIT "A"

This Emergency Contraception Drug Therapy collaborative Agreement was developed using the collaborative agreements of Washington and California, who developed their guidelines from the American College of Obstetricians and Gynecologists and the World Health Organization and physicians, pharmacists and nurses. This Agreement has been approved by the Board of Pharmacy, State of Hawaii.

Emergency Contraception Drug Therapy Collaborative Agreement

Purpose: Permit the use of drug therapy within 120 hours of the patient having unprotected sexual contact and to ensure the patient receives adequate information to successfully complete drug therapy.

Procedures: When the patient's pharmacist requests drug therapy, the pharmacist shall assess the need for drug therapy and/or referral for contraceptive care and reproductive health care. The pharmacist shall determine the following:

- 1. The date of the patient's last menstrual period to rule out established pregnancy;
- 2. Whether the elapsed time since unprotected intercourse is less than 120 hours;
- 3. Whether the patient has been a victim of sexual assault; and
- 4. That the patient is at least 14 years of age.

Referrals: The licensed pharmacist shall refer the patient to the licensed physician for follow-up. If drug therapy services are not available at the pharmacy, the pharmacist shall refer the patient to another licensed pharmacist. Also, the pharmacist shall refer the patient to see either a medical doctor or family planning clinic provider if:

A. The pharmacist cannot rule out that the patient is pregnant or if the elapsed time since the patient having unprotected intercourse is greater than 120 hours;

- B. The pharmacist is concerned that the patient may have been exposed to a sexually transmitted disease;
- C. The patient does not have a regular contraceptive method; and
- D. The patient does not have a health care provider and needs free or low cost family planning services.

If the pharmacist is concerned that the patient may have contracted a sexually transmitted disease through unprotected sexual activity and/or if the patient indicates that she has been sexually assaulted, the pharmacist may recommend referral to a medical doctor, a family planning clinic, a sexual assault treatment center, the police, or multiple referrals to these entities as the pharmacist may deem appropriate, while providing drug therapy.

While drug therapy can be used repeatedly without serious health risks, patients who request drug therapy shall be referred to a medical doctor or family planning clinic provider for consideration of the use of a regular contraceptive method.

Drug Therapy product selection: The pharmacist shall provide medication from a list of drugs approved for emergency contraception by the United States Food and Drug Administration ("FDA") listed in Exhibit "B" and agreed upon as part of this collaborative Agreement. Plan B® shall be the preferred drug therapy. The list shall include emergency contraceptives and adjunctive medications for treatment of nausea and vomiting associated with emergency contraceptives. The list shall be maintained at the pharmacy and shared by all participants in the agreement. Along with the medication, the pharmacist shall provide drug information concerning dosage, potential adverse effects, and follow-up contraceptive care.

Prescription labeling: The label placed on the drug therapy product shall contain the names of both the pharmacist and the physician signers of this Agreement.

Documentation: Each drug therapy prescription authorized by the physician and initiated by the pharmacist shall be documented in a patient profile.

Training: The pharmacist who participates in the drug therapy shall have received appropriate training that includes programs approved by the American Council of Pharmaceutical Education (ACPE), curriculum-based programs from an ACPE-accredited college of pharmacy, state or local health department programs, or programs recognized by the board of pharmacy. Training must include procedures listed above, the management of the sensitive communications often encountered in emergency contraception, service to minors, quality assurance, referral for additional services, documentation and a crisis plan if the pharmacy operations are disrupted by individuals opposing the emergency contraception.

Further, the pharmacist agrees to participate in the Emergency Contraception Hotline.

Term of the Agreement: This agreement shall be effective for a period of at least two years from the date of its delivery to the Department unless rescinded in writing earlier by either the physician or the pharmacist, with written notice to the other and to the Department, or unless the Pharmacy Board invalidates such Agreement or changes the terms of the agreement. After the two year period, the agreement shall continue to be valid month to month unless rescinded, invalidated, or changed as provided herein. The licensed pharmacist or the licensed physician, who rescinds the agreement, shall notify the Department within three business days of the rescission. At the time the collaborative agreement is rescinded, the licensed pharmacist shall not have prescriptive authority to dispense emergency contraceptives until another collaborative agreement with a physician is completed and delivered to the department.

Additional Terms or Limitations:	
1)	
Physician's Name:	· · · · · · · · · · · · · · · · · · ·
Street Address/City/State; Zip Code:	
Phone Number:	MD License No.:
Physician's Signature:	Date:
Pharmacist's Name:	
	re Drug Therapy will occur (include name of pharmacy, -charge and pharmacist-in-charge license number):
	Pharmacist License No.:
·	e n
3	e e
Phone Number:	_
Pharmacist's Signature:	Date:
Pharmacist-in-charge's Signature:	Date:

$(Name\ of\ Pharmacy)\\ \textbf{Informed\ Consent\ for\ Emergency\ Contraception\ Drug\ Therapy}$

Name of Patient:	Age:
Address:	
Phone No.:	2 D
First day of last menstrual period:/_/ Mo/Day/Year	
Date of unprotected sexual intercourse:/_/ Mo/Day/Year If more than one exposure, give date and time of initial exposure:	eq.
	Yes No
was this sexual intercourse the result of sexual assuart.	100
Before giving your consent, be sure that you understand both the contraceptive Pills (ECPs). If you have any questions, we will be <u>Do not sign</u> your name at the end of this form until you have read pharmacist has answered your questions and can witness your sig confidential.	e happy to discuss them with you. and understood each statement and the
 I understand that: ECPs contain hormones that act to prevent pregnancy. unprotected sex (sex without birth control or birth control emergency treatment only and not as a routine method of 2. ECPs work by preventing or delaying the release of an fertilization, or causing changes in the lining of the uterus fertilized egg. I understand that if I am already pregnant, pregnancy. ECP treatment should be started within 5 days (120 how to be a started within 5 days). Reactions to the pills may include: nausea and vomiting early or late menstrual period. 	I failure). They are to be used as an contraception. I egg from the ovary, preventing so that may prevent implantation of a ECPs will not stop or interfere with the cours) of unprotected sex.
 6. I should see a physician if my period has not started w 7. I should use condoms, spermicides, or a diaphragm, or prevent pregnancy if I have sex before my next period. A method of contraception. 8. ECPs will not protect me from or treat sexually transmediagnosis and treatment if I am concerned because I have month or my partner has had sex with someone else in the sexually transmitted disease. 9. I understand that it may be useful to share this treatment care provider. Therefore, I request and authorize the reledesignated provider: 	After that, I should continue to use a mitted diseases and I should seek had sex with a new partner in the past e past month or my partner has a ent information with my regular health ease of this information to the following
*	Yes No
10. Designated Provider's Name:	
Patient's Signature:	Date:

Informed Consent for Emergency Contraception Drug Therapy Continued Pharmacist's Signature: _______ Date: ______ Pharmacist only: Referral made to: _______ Rx No.: ______

Screening Checklist for Emergency Contraceptive Pills

Patient Name:	loday's Date:
Address:	Age:
These questions are to help us	understand what you need right now.
1. Have you had unprotected sex during the last	5 days? Yes No
2. On what day(s) did you have unprotected sex	in the past 5 days?
Monday Tuesday Wednesday The	ırsday Friday Saturday Sunday
3. What time of day was the first unprotected sex	in the past 5 days? A.M P.M.
4. Have you had unprotected sex prior to the last	five days? Yes No
5. When was the first day of your last menstrual	period? Date:
Condoms Diaphra IUD Other M Contraceptive Shot (Depo Provera®) 7. Did you have unprotected sex as a result of se	ontrol Pills lgm lethod
when you didn't want to?)	Yes No
8. Would you like a pharmacist to call you in the	e next couple of weeks to see how you're doing? Yes No y is best to call? A.M P.M.
	*
Patient's Signature:	Date:
For Pharmacist Use Only	
Date and time of interview:	EC Provided: Yes No
	ion for STD Other medical evaluation Counseling No referrals made
Date and time of callback:	Referrals made then?
Pharmacist's Signature:	Date:

EXHIBIT "B"

Brands and Doses

Of Oral Contraceptive Pills Used For Emergency Contraception

There are now two prepackaged emergency contraceptive pill products (dedicated emergency contraceptive pills) as well as 14 brands of birth control pills that can be used for emergency contraception.

Brand	Manufacturer	Pills per Dose (Treatment schedule is one dose ASAP after unprotected intercourse, and a second dose 12 hours later)	Ethinyl Estradiol per Dose (mcg)	Levonorgestrel per Dose (mg)*
Dedicated Emery	gency Contraceptive H	Pills		
Plan B	Women's Capital Corporation	1 white pill	0	0.75
Preven	Gynetics	2 blue pills	100	0.50
Oral Contracept	and the contract of the contra		T-120	10.50
Levora	Watson	4 white pills	120	0.60
Levlen	Berlex	4 light-orange pills	120	0.60
Lo/Ovral	Wyeth-Ayerst	4 white pills	120	0.60*
Low-Ogestrel	Watson	4 white pills	120	0.60*
Nordette	Wyeth-Ayerst	4 light-orange pills	120	0.60
Alesse	Wyeth-Ayerst	5 pink pills	100	0.50
Aviane	Duramed	5 orange pills	100	0.50
Levlite	Berlex	5 pink pills	100	0.50
Ogestrel	Watson	2 white pills	100	0.50*
Ovral	Wyeth-Ayerst	2 white pills	100	0.50*
Tri-Levlen	Berlex	4 yellow pills	120	0.50
Triphasil	Wyeth-Ayerst	4 yellow pills	120	0.50
Trivora	Watson	4 pink pills	120	0.50

Adapted from RA Hatcher, et al, Contraceptive Technology: Seventeenth Revised Edition. New York NY: Ardent Media, 1998. Updated by Felicia Steward, MD 2001.

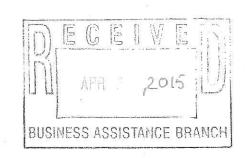
^{*} This progestin in Ovral, Lo/Ovral, Low-Ogestrel, Ogestrel and Ovrette is norgestrel, which contains two isomers only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel.

Anti-nausea Treatment Options for use with Emergency Contraception

Drug	Dose	Timing of Administration
Non-prescription Drugs		
Meclizine hydrochloride (Dramamine, Bonine)	One or two 25mg tablets	1 hour before first EC dose; repeat if needed in 24 hours
Diphenhydramine hydrochloride (Benadryl)	One or two 25mg tablets or capsules.	1 hour before first EC dose; repeat as needed every 4-6 hours.
Dimenhydrinate (Dramamine)	One or two 50mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first ECP dose; repeat as needed every 4-6 hours.
Cyclizine hydrochloride (Marezine)	One 50mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours.

Adapted from RA Hatcher, et al, *Contraceptive Technology: Seventeenth Revised Edition*. New York NY: Ardent Media, 1998. Updated by Felicia Steward, MD 2001.

Exhibit 2



Amendment to Chapter 13-146 Hawaii Administrative Rules

DATE

1. Chapter 13-146, Hawaii Administrative Rules, is amended by adding a new section to read as follows:

§ 13-146-6 Fees. (a) The following fees are hereby established:

STATE PARK CAMPING FEES:

For all state parks that allow camping, except for the Napali Coast State Wilderness Park, the camping fee shall be as follows:

Residents:

\$12 per night per camp site (up to six people) \$2 per night for each additional person, with a maximum of ten people total per camp site

Nonresidents:

\$18 per night per camp site (up to six people) \$3 per night for each additional person, with maximum of ten people total per camp site

NAPALI COAST STATE WILDERNESS PARK

Residents: \$15/person per night
Nonresidents: \$20/person per night

CABIN RENTAL FEES:

HAPUNA BEACH STATE RECREATION AREA
Residents: \$30/night per A-Frame
Nonresidents: \$50/night per A-Frame

KALOPA STATE RECREATION AREA, POLIPOLI SPRINGS STATE RECREATION AREA, WAI 'ANAPANAPA STATE PARK Residents: \$60/night per cabin

Non-residents: \$90/night per cabin

FEES FOR CHANGE OR CANCELLATION OF CAMPING OR RENTAL CABIN RESERVATIONS:

\$3 per change \$5 per cancellation

WAILOA STATE RECREATION AREA DAY USE PAVILIONS

Large	pavilions:	\$125	renta	l f	ee,	wit	h a	\$150
		depos	sit					
Small	pavilions:	\$5/h	our, w	ith	а	\$50	dep	osit

PARKING FEES

NU'UANU PALI STATE WAYSIDE			
Residents:	No c	harge	
Nonresidents:		\$3	(1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -
Commercial PUC vehicles:			
1-7 passenger vehicles:		\$6	C
8-25 passenger vehicles:		\$12	
26+ passenger vehicles:		\$24	34
11			
IAO VALLEY STATE MONUMENT			
Residents:		No c	charge
Nonresidents:		\$5	
Commercial PUC vehicles:			
1-7 passenger vehicles:		\$10	
8-25 passenger vehicles:		\$20	
26+ passenger vehicles:		\$40	
MAKENA STATE PARK			
Residents:		No c	charge
Nonresidents:		\$5	
Commercial PUC vehicle fees:			
1-7 passenger vehicles:		\$10	
8-25 passenger vehicles:		\$20	
26+ passenger vehicles:		\$40	
HAPUNA BEACH STATE RECREATION	AREA		
Residents:			charge
Nonresidents:		\$5	

Commercial PUC vehicles: 1-7 passenger vehicles:	\$10)	
8-25 passenger vehicles:	\$20	_	
26 + passenger vehicles:	\$40		
ENTRANCE FEES			
DIAMOND HEAD STATE MONUMENT			
Daily Rates:			
Pedestrians:	\$1		
Noncommercial vehicles (except mopeds):	\$1 \$5 \$1 \$1		
Mopeds:	\$1		
Others (not listed):	\$1		
Commercial Vehicles: 1-15 passenger-capacity vehicles: 16-25 passenger-capacity vehicles:	\$10 \$20	<u>)</u>	
26+ passenger-capacity vehicles:	\$40	5	
Annual Pass: Pedestrians: Private vehicles:	\$10 \$30	<u>)</u>	
AKAKA FALLS STATE PARK			
Residents:	No	chai	rge
Nonresidents:	\$5	per	vehicle
Others (not listed):	\$1	per	person
Commercial PUC vehicles:			
1-7 passenger vehicles:	\$10		
8-25 passenger vehicles:	\$20	<u> </u>	
26+ passenger vehicles:	\$40	<u>)</u>	
WAIMEA CANYON STATE PARK AND KOKEE STATE			
Residents:		chai	
Nonresidents:	\$5		vehicle
Others (not listed):	\$1	per	person
Commercial PUC vehicles:	41.	0	
1-7 passenger vehicles:	\$1		
8-25 passenger vehicles:	\$2	<u>J</u>	
26+ passenger vehicles at Waimea Canyon State Park:	\$4	0	\$7 \$7
at warmed carryon state rark.	74	_	

HA'ENA STATE PARK

Residents:	No charge
Visitors:	\$5 per vehicle
Others (not listed):	\$1 per person
Commercial PUC vehicles:	
1-7 passenger vehicles:	\$10
8-25 passenger vehicles:	\$20
26+ passenger vehicles:	\$40

(b) For purposes of this section, the following definitions shall apply:

"Commercial PUC vehicle" means a vehicle that is regulated by the Hawaii Public Utilities Commission.

"Resident" means a resident of the State with a
valid State of Hawaii identification card or State of
Hawaii driver's license." [Eff] (Auth: HRS
\$\sums\$ 184-3, 184-5) (Imp:)

- 2. New material is underscored.
- 3. The amendments to chapter 13-146, Hawaii Administrative Rules, shall take effect ten days after filing with the Office of the Lieutenant Governor.

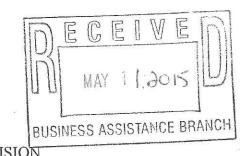
I certify that the foregoing are copies of the rules, drafted in the Ramseyer format pursuant to the requirements of section 91-4.1, Hawaii Revised Statues, which were adopted on ______ by the Board of Land and Natural Resources, and filed with the Office of the Lieutenant Governor.

CARTY S. CHANG, Chairperson Board of Land and Natural Resources

APPROVED FOR PUBLIC HEARING:

Deputy Attorney General

Exhibit 3



DEPARTMENT OF FINANCE COUNTY OF KAUA'I REAL PROPERTY ASSESSMENT DIVISION

REAL PROPERTY TAX CLASSIFICATION RULES

Administrative Rules of the Director of Finance Relating to Real Property Tax Rate Classifications under Section 5A-6.4 of the Kauai County Code 1987, as amended.

- §RP-12-1 <u>Purpose.</u> These rules implement the provisions of Section 5A-6.4 of the Kauai County Code ("K.C.C.") relating to tax rate classification. These rules are further intended to ensure that the referenced provisions are applied in a uniform and equitable manner. These rules and any definitions in these rules apply only to K.C.C. § 5A-6.4.
- §RP-12-2 <u>Authority.</u> These rules are promulgated pursuant to K.C.C. § 5A-1.2(j) under the Director of Finance's authority to effectuate the purpose of K.C.C. § 5A-6.4.
- §RP-12-3 <u>Retroactive effective date.</u> These rules shall be effective and applied retroactively to the furthest extent allowable by law.
- §RP-12-4 **<u>Definitions.</u>** As used in these rules, except as otherwise required by context:
- "Actual use" means how the owner uses the property as of the date of assessment.
- "Definite established uses" includes categories of actual uses included in a general class, but the general class is not limited to the included definite established uses.
- "Home office" means a portion of the taxpayers' property dedicated to work-related activities but is not advertised or operated as a place of business.
- "Household" means a single person or a number of related or unrelated people who reside in a living unit.
- "Living unit" means an apartment, condominium, house, portion of a house, or structure occupied by a household.
- "Long term rental" means a residential rental agreement for a period of at least one hundred and eighty days. This also includes month to month tenancy, if it is the same tenant for at least one hundred and eighty days. Rental agreements must be signed by the owner, signature by the owner's agent is not sufficient.

"Owner" is defined in K.C.C. § 5A-7.1.

"Place of business" means a structure where a person engages in a trade or business evidenced by customer parking, client traffic, advertising, or signage. "Principal residence" means the primary location that a person inhabits. Criteria for determination of a principal residence are outlined in the Department of Finance Home and Related Exemption Rules Section RP-10.4. "Productive" means producing a benefit or income, which depend on the physical attributes, locational attributes, legal entitlements, or improvements. "Short term rental" means a residential rental agreement for a period of less than one hundred and eighty days.

- §RP-12-5 **Procedure.** Real property shall be classified into a general class provided in K.C.C. § 5A-6.4 for tax rate purposes. Assignment to a general class is based on the actual use of the property on October 1st preceding each tax year.
- §RP-12-6 <u>Clarification of general classes</u>. The general classes are defined and definite established uses for tax classification are provided. The definite established uses provided are not exhaustive. If a property's actual use is included in the definite established uses, the property shall be assigned to that class. If a property's actual use is not found in the definite established uses, or a definite established use is not provided, the definitions as well as definite established uses are to be read together to properly classify a property.
 - (a) "Residential" includes use as a residence.
 - (1) Definite established uses: long-term rental, second home exclusively used by the owner(s), vacant residential structures, and a part time residence not occupied as a principle residence.
 - (b) "Vacation rental" includes the renting out of an apartment, condominium, living unit or house on a temporary basis to a person(s) as an alternative to a hotel for a period of less than one hundred-eighty consecutive days.
 - (1) A property subject to the Hawai'i Transient Accommodation Tax, other than those classified as Hotel & Resort, will be considered a vacation rental.
 - (2) Advertising of any sort which offers a property or portion of a property as a vacation rental or short term rental shall constitute prima facie evidence of the operation of a vacation rental.
 - (c) "Commercial" includes the use of the property to generate income, monetary gain or economic benefit.
 - (1) Definite established uses: golf course, retail space, commercial office space, shopping centers, strip malls, hospital facilities, medical offices, dental offices, restaurants, theatres, fitness centers,

churches, schools, recreational enterprises conducted for profit, amusement enterprises conducted for profit, ceremonial enterprises conducted for profit, places where commodities or services are offered for sale, and spa facilities.

- (2) The retail sale of products grown and sold on agricultural lands does not constitute a commercial use, unless a commercial use permit is granted. However, the retail sale of any other product constitutes commercial use.
- (3) Commercial use does not include a home office as defined in these rules.
- (d) "Industrial" includes pertaining to manufacturing or processing, including the performance of mechanical or chemical operations.
 - (1) Definite established uses: manufacturing facilities, warehouse space, auto repair, paint or body shops, chemical production, chemical storage, mini-storage space, energy production facilities, communication towers, and processing and packing facilities.
- (e) "Agricultural" includes the science or practice of farming, including cultivation of the soil for the growing of crops and the rearing of animals to provide food, wool, and other products.
 - (1) Definite established uses: farming or plant cultivation, ranching livestock, beekeeping, dairy farming, forestry, aquaculture, plant nurseries, horticulture structures, equestrian buildings, agricultural production facility, agricultural packaging facility, and farm worker housing.
- (f) "Conservation" is a classification reserved for vacant properties zoned within a conservation state or county land use district.
- (g) "Hotel and Resort" includes an establishment providing rooms and amenities for transient tenants as a place where people go for rest, recreation, or sport.
 - (1) Definite established uses: hotel operations, resorts, motels, and timeshare units.
- (h) "Homestead" means a property which is used exclusively as the owner's principal residence, provided that the owner has been granted a home exemption according to K.C.C. § 5A-11.4.
 - (1) Criteria for qualification:
 - (A) The property must be the owner's principal residence.
 - (B) Submittal of a State of Hawai'i Resident Income Tax Return, or any other sufficient documentation approved by the Director of Finance, with a reported address in the State of Hawai'i.

- (i) Sufficient documentation may include the documents referred to in Section RP-10.4, Home and Related Exemption Rules.
- (ii) If the owner is not required to file an Income Tax Return, a notarized affidavit must be filed indicating the owner's principle address and indicating the dates of residency in the County of Kaua'i.
- (iii) Non-resident and part-year resident State of Hawai'i income tax returns do not qualify for the home exemption.
- (2) Properties that have multiple living units must have owneroccupants with qualified home use exemptions and long-term affordable rental occupants in the other living units to be eligible.
- (3) Principal residence properties that have either agriculturally dedicated lands or licensed day cares located on the same property and no other additional uses may be eligible.
- (4) A home office, defined in these rules, may be included in a homestead.
- (i) "Residential Investor" is a classification for residential properties that do not qualify for the home exemption, are improved with a dwelling unit(s), not vacant land, and have an assessed value of two million dollars (\$2,000,000.00) or more.
 - (1) This class does not include a property were all living units are rented on a long term rental basis.
- (j) "Commercialized Home Use" is applicable to parcels utilized for multiple purposes, one of which is use as the taxpayer's principal residence as of the date of assessment, provided that the taxpayer has been granted a home use exemption on the property pursuant to K.C.C. § 5A-11.4.
- §RP-12-7 <u>Vacant land.</u> Vacant land shall be classified as zoned until actual use is established. If the property has multiple zonings, then an assessment is made for each zoning.
- (a) "Vacant land" means unimproved land, or a portion of the property verified by a special use permit, that lacks the essential appurtenant improvements required to make it productive.
- (b) The following general classes are zonings for vacant land and actual uses: residential, commercial, industrial, agricultural, and hotel and resort.
- §RP-12-8 <u>Partially Complete.</u> A partially complete property shall be classified as zoned until actual use of the improvements has been established.

- (a) "Partially complete" means a property, that shall be added to the assessment list pursuant to K.C.C. § 5A-8.1(e), where active construction exists, but has not yet been completed establishing the actual use. This includes structures with completion between twenty percent (20%) and sixty nine percent (69%). Completion percentage is determined by the "Appraisal and Component Rating Worksheet for Incomplete Buildings" incorporated into these rules by reference. This worksheet is available from the Real Property Assessment Division.
 - (b) At seventy percent (70%) completion, actual use may be established.
- §RP-12-9 <u>Criteria to change tax classification</u>. The following proof must be submitted, if applicable, to the Real Property Assessment Division by September 30th of the year prior to the desired change.
 - (a) Cessation of all previous use on the property.
 - (b) Removal of all signage indicating the previous use of the property.
- (c) Removal of all advertisements, referencing the previous use of the property.
- (d) A copy of the County of Kaua'i Planning Department's closing letter or email acknowledging compliance with any use violations.
 - (e) A newly completed Use Survey indicating current actual use(s).
 - (f) Affidavit from the owner describing the current use(s) of the property.
- (g) Additional requirements to change from a "Vacation Rental" to a different class.
 - (1) Acknowledgment by the County of Kaua'i Planning Department that the transient vacation non-conforming use permit is forfeited.
 - (2) An affidavit indicating the last pre-paid or reserved booking of the vacation or short term rental use on the property.
 - (3) Proof of cancellation of Transient Accommodations Tax License.
 - (4) A copy of a current long term lease and most recent general excise tax license filing.
- §RP-12-10 <u>Appeal.</u> The owner may appeal the property's tax rate classification as in the case of an appeal from an assessment, as provided in K.C.C. § 5A-6.4(g).
- §RP-12-11 <u>Severability.</u> If any provision of these rules or the application thereof to any person or circumstance is held invalid, the invalidity shall not affect other provisions or applications of these rules which can be given effect without

the invalid provision or application, and to this end the provisions of these rules are declared to be severable.